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National Agency for Medicines and Medical Devices

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Order	860	21.05.2020	22.05.2020	
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Order	503	26.03.2020	27.03.2020	

Ministry of Health

Order no. 487
of 23 March 2020

on approval of the protocol for treatment of the infection with the SARS-Cov-2 virus

On seeing the Approval report of the General Directorate for Medical Assistance and Public Health of the Ministry of Health no. VSC 3.987 of 23.03.2020,

taking into account provisions of Article 16 (1) g) of Law 95/2006 on healthcare reform, republished, as amended,

provisions of Decree no. 195/2020 on establishment of the state of emergency in Romania,

pursuant to Article 7 (4) of Government Decision No. 144/2010 on organisation and operation of the Ministry of Health, as amended,

the minister of health hereby issues the following Order**:**

Article 1 – The protocol for treatment of the infection with the SARS-Cov 2 virus is hereby approved, as provided in the Annex.

Article 2 – The special directorates of the Ministry of Health, public and private health units, as well as the medical staff involved in providing medical services related to the involved areas will lead to the implementation of this Order's provisions.

Article 3 - The Annex is integral part of this Order.

Article 4 - This Order shall be published in the Official Gazette of Romania, Part I

p.p. the Minister of Health,
Horaţiu Moldovan,
Secretary of State

Annex

TREATMENT PROTOCOL
for the SARS-CoV-2 infection

Taking into account the appearance of the SARS-CoV-2 epidemic at the end of 2019 in China and its pandemic expansion, as well as the increase in the number of COVID-19 cases in Romania, including severe forms of the disease, it is necessary to develop a protocol treatment that takes into account the data accumulated so far. This protocol addresses the general situation of patients with COVID-19, without addressing particular situations in detail. In order to carry out this protocol, the provisions of the documents issued by the World Health Organisation (WHO) and the European Centre for Disease Prevention and Control (ECDC), of the therapeutic guidelines elaborated in China, Italy, Belgium and other materials published since setup of the previous version were analysed.

Through the recommendations on the care of patients with SARS-CoV-2 infection, this protocol represents a support for the decisions of the medicinal product policy commissions within health units regarding the "off-label" use of some potentially active medicinal products, in accordance with Article 27 of Decree no. 195/2020 on establishment of the state of emergency in Romania.

This therapeutic protocol includes principles grouped in the following sections:

I. Antiviral medication
II. Immunomodulatory medication, including convalescent plasma
III. Management of coagulation disorders in patients with COVID-19
IV. Antibiotics and other antiinfective medicinal products
V. Support of vital functions
VI. Other therapeutic measures

I. Antiviral medication

The evolution of COVID-19 has an initial phase dominated by viral replication, with a variable duration; during this time, the patient goes through a presymptomatic period in order to become symptomatic. Antiviral medication should be administered as soon as possible after diagnosis (preferably from the beginning of the symptomatic period), aiming at:

- limiting the risk of the patient's transition to the phase dominated by inflammatory manifestations, in which severe manifestations of disease occur more frequently;

- reducing the duration of the disease, shortening the patient's hospitalisation, which increases patient safety, thus reducing the impact on consumption of hospital care resources per patient.

People infected with SARS-CoV-2 who remain asymptomatic throughout the course of the infection do not receive treatment, as it has not been shown that this would reduce the duration of excretion of the virus.

Potentially active antivirals against SARS-CoV-2

- (hydroxyl)chloroquine

Hydroxychloroquine has demonstrated in vitro activity against SARS-CoV-2, as well as some positive results in the treatment of patients with COVID-19. Yao X and colleagues have discovered that, compared to chloroquine, hydroxychloroquine inhibits SARS-CoV-2 7.6 times more effectively in vitro. Hydroxychloroquine is better tolerated than chloroquine and has fewer medicinal product-medicinal product interactions; in addition, it has been widely used in long-term treatments in rheumatology, without generating significant side effects. The molecular mechanisms of action of chloroquine and hydroxychloroquine have not been fully elucidated. First, the two medicinal products can alter the pH of the cell membrane surface and thus inhibit

the fusion of the virus to the cell membrane. Moreover, they can inhibit nucleic acid replication, glycosylation of viral proteins, virus assembly, and virus release from the infected cell. Data published on 17 March 2020 by the group coordinated by Gautret C. which evaluated 42 patients indicate a faster virus clearance in patients with COVID-19 who have received hydroxychloroquine.

The balance of possible benefits / risks (in vitro efficacy, possible clinical efficacy and reduced risk of adverse effects) has placed hydroxychloroquine as an antiviral therapeutic alternative at this stage of the COVID-19 pandemic, which led to an interim authorisation for use in the USA.

- Protease inhibitors

Lopinavir is a protease inhibitor used to treat the HIV infection in combination with ritonavir in order to increase its availability. Lopinavir has some degree of activity against in vitro coronaviruses, including SARS-CoV-2. The clinical data published so far are inconsistent. Three observational studies failed to identify a reduction in the duration of virus excretion in patients treated with lopinavir / ritonavir compared to favipiravir or placebo, while the use of lopinavir / ritonavir resulted in faster elimination of the virus during the Wuhan epidemic, in the case of early administration, in the initial viral phase (the first 10 days after the onset of symptoms). In a randomized clinical trial on 200 patients with moderate to severe disease, Cao and colleagues have showed that lopinavir / ritonavir caused a faster regression of symptoms and reduced the death rate, with no difference in statistical significance; it should be noted that initiation of the viral treatment was relatively late in this study. In another single-blind trial (ELACOI Trial) performed on 44 patients with mild to moderate disease, lopinavir / ritonavir had more side effects and did not reduce the duration of viral excretion compared to umifenovir or placebo. These outcomes, although an insufficient number of patients may be reported for a disease with low mortality, have led to a decline in the use of lopinavir / ritonavir for the treatment of COVID-19. However, considering the existing favourable data, this medicinal product remains an alternative, in the absence of more effective products. An additional benefit is the liquid form of administration - usable in patients who received orotracheal intubation and in newborns.

Darunavir / Cobicistat and atazanavir / ritonavir have been used as alternatives for patients intolerant to lopinavir / ritonavir, but experience with these substances is much more limited; the darunavir / cobicistat manufacturer claims that this product is in vitro ineffective against SARS-CoV2 and discourages its use in patients with COVID-19, therefore its use should be avoided.

- Remdesivir

Remdesivir is another potentially useful antiviral for the treatment of COVID-19, which inhibits RNA-dependent RNA polymerase, prematurely blocking RNA transcription. It has in vitro activity against coronaviruses, including SARS-CoV-2. The medicinal product has completed a phase III clinical trial for the treatment of Ebola infection and there is relatively detailed pharmacokinetic data for the human body. Data obtained in clinical trials in treatment of COVID-19 was contradictory; Wang et al. included 237 patients in a comparative study on remdesivir versus placebo, which was prematurely discontinued due to lack of efficacy and an increased rate of side effects: 12% versus 5% placebo. In another study involving 1063 severely ill patients treated with remdesivir versus placebo, there was a discrete benefit in terms of mortality: 8% versus 11.8% ($p = 0.06$) and duration until improvement: 11 days compared to 15 days, $p = 0.01$. An advantage for use in severe forms is its parenteral administration. It is currently used in clinical trials and can only be obtained for individual compassionate use for pregnant women or children with severe forms of COVID-19. An "early access" programme is also being developed in several countries of the European Unit, through which the national authority manages the use of remdesivir, based on a scientific recommendation developed by the EMA.

- Other potentially active antivirals

Umifenovir works against influenza viruses and is used in this indication in Russia and China; its antiviral action is based on blocking the penetration of the virus into the cells (fusion inhibitor) and on the immunomodulatory effect. Its advantage consists of reduced side effects. In the SARS-CoV-2 epidemics in China, umifenovir was used in combination with other antiviral medicinal

products; Deng L. et al. found that, in patients with uncomplicated pneumonia in COVID-19, the association of umifenovir (200 mg every 8 hours) with lopinavir / ritonavir allowed faster nasopharyngeal clearance and a faster regression of pulmonary imaging changes compared to the regression in patients receiving lopinavir / ritonavir monotherapy. There are currently two ongoing clinical trials evaluating the effect of umifenovir compared to the effect of lopinavir / ritonavir, namely to the standard antiviral-free treatment. Umifenovir can also be used in children over 12 years of age for SARS-CoV-2 infection; for other viral infections, it can be used from the age of 2 years (25% of adult doses for children aged 2 to 7 years and 50% of adult doses for children aged 7 to 12 years).

Given the favourable results reported and the low rate of adverse effects associated with its administration, umifenovir represents a solution; it should be used in association with another antiviral that is more difficult to tolerate (lopinavir / ritonavir, remdesivir or hydroxychloroquine).

Favipiravir is an RNA polymerase inhibitor that has been used for influenza and the Ebola infection. It was originally manufactured in Japan, but used more frequently in China; due to its teratogenic effects, its use is only allowed for special situations such as epidemics or emerging infections with influenza viruses, in Japan. As regards the SARS-CoV-2 infection, favipiravir was more efficient in terms of viral eradication and regression of lung imaging than both lopinavir / ritonavir and umifenovir; the doses used were 1,600 mg every 12 hours on the first day, then 600 mg every 12 hours for 7-14 days. The medicinal product cannot be administered to children, men in the period of maximum fertility (it accumulates in semen) and pregnant women (teratogenic risk); it was used in China in female patients of childbearing age only if their pregnancy test result was negative and always in association with contraceptive medication during treatment and at least 7 days after ending the treatment; men were advised to use a condom for at least one week after discharge.

Given the selective inclusion criteria, the need to inform patients, the need for additional testing and the administration of contraceptives which may have significant interactions with other medicinal products, favipiravir remains a therapeutic alternative when other antivirals are not available and all conditions mentioned for safe administration are met - for example, in menopausal patients.

- Neuraminidase inhibitors

The administration of oseltamivir, peramivir or zanamivir is not justified in the treatment of COVID-19, as this virus does not have neuraminidases; it is recommended to combine the anti-influenza medication (oseltamivir is available in Romania) in patients with COVID-19 until the diagnosis of influenza is excluded by gene amplification test or as long as necessary for treatment of a concomitant infection with an influenza virus.

To conclude, antiviral treatment should be started as soon as possible after the onset of symptoms and will include two antivirals, as there is no certain data on the high efficacy of any of the usable ones, and their choice will depend on possible side effects and pathologies of the patient, as well as on the accessibility of one or the other antivirals at a given time. The route of administration also influences the choice of antivirals - preferably i.v. remdesivir and / or lopinavir / ritonavir syrup for patients with severe (intubated) forms.

II. Immunomodulatory medication

In some patients, the initial infectious phase is followed by a second stage, in which the inflammatory-immune response is exacerbated; clinically, this phase is associated with recrudescence / worsening of symptoms, particularly pulmonary ones; a significant proportion of the cases with unfavourable evolution is represented by patients with an excessive inflammatory response ("cytokine storm"), who are often adults without known previous pathologies. At the same time, another subgroup of patients may have a deficiency in immunity which prevents the control of the SARS-CoV-2 infection and predisposes to superinfections (patients in the classic risk groups are more common here).

Extensive biological monitoring is important in order to seize the moment of the inflammatory reaction, with the help of the C-reactive protein, LDH, blood test (lymphocytes, platelets), ferritin, IL-6, fibrinogen, D-dimers.

The administration of immunomodulatory medication seeks to reduce the risk of unfavourable evolution, including death, in these categories of patients. The expected beneficial effects can be counterbalanced by intense immunosuppression, with delayed eradication of the SARS-CoV2 infection and possible reactivation of chronic infections: tuberculosis, pneumocystosis, HSV, chronic viral hepatitis.

The main therapeutic essays for this purpose were based on: systemic corticosteroids, immunosuppressive medicinal products / modulators, convalescent plasma.

Systemic corticosteroids

Results in patients with SARS-CoV-1 infection were analysed in several studies: 25 studies did not provide conclusive results, and a worsening of the disease was found in 4 other studies.

Alternatively, corticosteroids are the main treatment in the control of the excessive cytokine release syndrome. Used in patients with acute respiratory distress in COVID-19, corticosteroids significantly reduced lethality to 46% versus 62% in those who did not receive corticosteroids. The specific indication applies to cases of COVID-19 with excess inflammation and possibly developing pneumonia, when the administration should be initiated as early as possible: methylprednisolone (1-2 mg / kilogram body weight / day) or dexamethasone, 16-20 mg / day, for 5-7 days.

The administration of corticosteroids is also justified in patients with COVID-19:

- in cases with other indication for use (for corticosteroids), such as asthma attack, exacerbated COPD or adrenal insufficiency;

- in cases of septic shock unresponsive to vasopressor amines (HHC, usually 50 mg every 6 hours).

Immunomodulators

- Tocilizumab

This IL-6 receptor antagonist has been used in a subgroup of patients with severe forms of COVID-19 with excessive inflammation activation ("cytokine storm"). The identification of patients who would benefit from tocilizumab can be based on parameters such as increased ferritin levels, decreased lymphocyte and platelet counts, increased C-reactive protein, fibrinogen, and D-dimer levels. There is data reported by Xu et al. on efficacy of tocilizumab in a number of 21 Chinese patients; following administration of 1-2 doses of tocilizumab, afebrility was obtained in all patients, as well as decreased oxygen demand, and partial correction of lymphopenia. In the clinical experience of the authors, the results obtained with tocilizumab in association with corticosteroids were favourable, following administration of 8 mg / kilogram body weight doses, repeated at 8 - 12 hours, up to a maximum of 3 administrations.

There are risks related to reactivation of tuberculosis, hepatic cytolysis, hypercholesterolemia.

- Baricitinib

Baricitinib is a JAK (Janus kinase) inhibitor used in treatment of moderate to high forms of rheumatoid arthritis (oral administration) at a standard dose of 4 mg / day with a low rate of infectious reactivation. Cantini F. et al. used baricitinib for 14 days in association with lopinavir / ritonavir for treatment of 12 patients with moderate pneumonia and COVID-19. Clinical improvements were obtained in all patients; in only one case, treatment was discontinued on day 10 due to hepatic cytolysis, more likely caused by lopinavir / ritonavir.

- Anakinra

Anakinra is an IL-1 receptor antagonist currently used in the treatment of rheumatoid arthritis and Still's disease; it is administered by subcutaneous route, 100 mg / day, but up to 400 mg / day can be administered in severe forms of inflammatory diseases. Off-label doses of up to 3,600 mg / day were used in the treatment of severe sepsis as a continuous infusion over several days without excessive side effects compared to the standard doses. In the case of COVID-19, subcutaneous or intravenous use of 200-400 mg / day has been proposed for several days (up to 10 days).

- The convalescent plasma will be used in accordance with the provisions of Order of the Minister of Health no. 654/2020 on approval of the Methodology for the collection, testing, processing, storage and distribution of plasma from the donor cured by COVID-19 and the monitored use for critically ill patients with COVID-19 in intensive care units.

III. Management of coagulation disorders in patients with COVID-19

Venous thromboembolism - VTE (deep vein thrombosis - DVT and pulmonary embolism - PE) is a common complication in acute infectious diseases; the risk of VTE is 2 - 32 times higher in such diseases.

The incidence of VTE in patients with COVID-19 has not yet been established. There are arguments demonstrating the association of a hypercoagulable state in patients with COVID-19. Hypercoagulability is related to the systemic inflammatory syndrome, endothelial dysfunction, an elevated factor VIII and von Willebrand factor. Given this hypercoagulable state, the risk of thrombosis increases by association of additional risk factors: pregnancy, prolonged immobilisation, dehydration, age, contraceptive use, obesity, associated diseases, cytostatics, surgical interventions, steroid therapy, etc.

The risk of VTE is significantly increased in patients admitted to intensive care - Klok demonstrates in a study on 184 patients admitted to intensive care in March-April 2020 an increased incidence of thrombosis complications (31%) in all age groups.

The aim of this document is to provide the clinician, who treats COVID-19 patients, with a set of general and specific recommendations on coagulation abnormalities and anticoagulant therapy:

A. General recommendations

1. Asymptomatic COVID-19 patients do not require routine anticoagulation. Exceptions are chronically anticoagulated patients (in whom the current therapy will be continued, making sure that it is administered in optimal doses and monitoring its efficacy where required) and patients with a high thromboembolic risk caused by other medical conditions.

2. All symptomatic COVID-19 patients have an indication for routine anticoagulation. The therapeutic regimen (prophylactic or curative) will be selected individually, depending on the thromboembolic risk class, considering the individual features and the bleeding risk.

3. The established scores for patients hospitalised with medical conditions, such as the PADUA score (table 1), can be used to calculate the thromboembolic risk; however, specific risk factors for COVID-19 patients should also be considered in the individual assessment: symptoms of respiratory failure, respiratory rate > 24 breaths / minute, SaO2 <90%, elevated CRP and fibrinogen levels, increasing D-dimer values - their presence placing patients at high risk.

4. Patients with high thromboembolic risk and low bleeding risk have an indication for curative anticoagulation. For patients admitted to ATI - it is preferable to choose unfractionated heparin (UFH) with a target activated partial thromboplastin time (APTT) of 60 - 85 sec. or alternatively enoxaparin 1 mg / kilogram body weight x 2 / day. For other patients hospitalised in infectious disease departments or other medical departments, enoxaparin 1 mg / kilogram body weight x 2 / day (or other low-molecular-weight heparin (LMWH) in equivalent dose) or Unfractionated

Heparin (UFH) with target activated partial thromboplastin time (APTT)of 60 - 85 sec is preferred.

5. The risk class is periodically re-evaluated, the modification of the clinical, biological or imaging picture requiring adjustment of the therapeutic decisions.

6. Patients with an indication for chronic oral anticoagulation require evaluation of medicinal product interactions, in which case switching to injectable anticoagulant (UFH or LMWH) is recommended at a therapeutic dose. In patients with metal valve prostheses, vascular prostheses or implantable cardiac devices, the choice of anticoagulant treatment will be decided after a cardiology consultation.

Table 1 – The Padua prediction score

Increased risk for venous thromboembolism ≥ 4

Clinical features	*Score*
Active cancer)*	*3*
History of pulmonary embolism / deep vein thrombosis	*3*
*Reduced mobility **)*	*3*
*Diagnosed thrombophilia ***)*	*3*
Trauma / Recent Surgery (≤ 1 month)	*2*
Age > 70 years	*1*
Heart/respiratory failure	*1*
Myocardial infarction / Ischemic stroke	*1*
Acute infection and / or rheumatic diseases	*1*
Obesity (BMI ≥ 30)	*1*
Hormone treatment	*1*

**) Patients with metastases and / or who have had chemotherapy or radiation therapy in the past 6 months.*

***) Immobilisation in bed (with the possibility of moving to the bathroom) either due to patient limitations or on medical recommendation, for at least 3 days.*

****) Antithrombin deficiency, protein C or S, factor V Leiden, G20210A prothrombin mutation, antiphospholipid syndrome*

B. Specific recommendations

1. Coagulation tests upon hospital admission:

D-dimers, prothrombin time, platelets - these parameters are used to classify patients with COVID-19 on risk groups. The clinician should be aware that there are many tools for determining D-dimers and great diversity in terms of the reference range, namely the units of measurement for the D-dimers level.

The D-dimers level indicating a negative prognosis is variable, depending on the study, the instrument used, the units of measurement.

In general, a 3-4-fold increase in D-dimer values is a negative prognosis (according to the ISTH guideline).

Other coagulation tests required: APTT, fibrinogen, INR, thrombin time, PDF.

The patient's history is very important, because the presence of diseases can be an explanation for certain coagulation-related abnormalities: haemophilia, thrombophilia, immune

thrombocytopenic purpura, liver cirrhosis, history of thrombosis, anticoagulant / antiplatelet therapy, diabetes, collagenosis, vasculitis.

2. Monitored coagulation tests

Regular repetition of the following tests is required: platelet count, prothrombin / PA / INR time, D-dimers, APTT, fibrinogen, antithrombin level (if possible).

The prolongation of PT, APTT, increase in D-dimers, decrease in fibrinogen and platelets indicate progression to disseminated intravascular coagulation (DIC). For the diagnosis of DIC, the ISTH (International Society of Thrombosis and Haemostasis) score is recommended - table 2.

Table 2

Parameters to be monitored	*Score*
Platelet count *> 100 x 10^9/L* *50 - 100 x 10^9/L* *< 50 x 10^9/L*	 *0* *1* *2*
D-dimers: *- regular* *- moderate increase (1 - 10 times the upper limit of normal)* *- strong increase (> 10 times the upper limit of normal)*	 *0* *2* *3*
Fibrinogen *> 1.0 g/L* *≤ 1.0 g/L*	 *0* *1*
Prothrombin time extended with: *< 3 seconds* *3 - 6 seconds* *> 6 seconds*	 *0* *1* *2*
True diagnosis of DIC	*Minimum 5 points*

The evolution towards DIC is a negative prognostic factor. According to the Tang study, 71.4% of deceased patients had DIC on day 4 and only 0.6% of survivors had this complication. Moreover, the authors observed a negative prognosis in patients who showed a significant increase in the level of D-dimers, prolongation of the TP and decrease in fibrinogen on day 10 and day 14, respectively.

If DIC is suspected, a peripheral blood smear (for schizocytes) and reticulocyte count are also required to demonstrate microangiopathic haemolytic anaemia.

3. Prophylactic anticoagulation in symptomatic patients hospitalised with COVID-19

The American Society of Haematology and the International Society of Haemostasis and Thrombosis recommend low-molecular-weight heparin (LMWH) prophylactic anticoagulation in all patients hospitalised for COVID-19, unless there are major contraindications (active bleeding). Prolongation of PT / INR or APTT is not a contraindication for anticoagulation, but it

will stop if the platelet count falls below 25 x 10^9 / L (25,000 / cubic millimeter) and / or the fibrinogen level drops below 0.5 g / L (47).

Equivalent (subcutaneous) dose of LMWH for thromboprophylaxis of low- or intermediate-risk patients (at the discretion of the attending physician):

- enoxaparin (clexane) - for patients with creatinine clearance (ClCr)> 30 mL / min, a single dose of 40 mg / day; for ClCr 15 at 30 mL / min - a single dose of 30 mg / day;

- dalteparin (fragmin) - a dose of 5,000 units / day;

- nadroparin (fraxiparin) - for patients with G ≤ 70 kg, a single dose of 3,800 or 4,000 anti-factor Xa units / day; for patients with G> 70 kg, a single dose of 5,700 units / day;

- tinzaparin (innohep) - a single dose of 4,500 anti-Xa units / day.

It is recommended to adjust the doses of LMWH according to certain particular clinical situations (associated diseases such as kidney disease, obesity).

Unfractionated heparin is recommended for patients with ClCr below 15 mL / min or on dialysis.

In patients with significant obesity or in other particular clinical and biological circumstances (at the discretion of the attending physician) the LMWH dose may be increased - enoxaparin 40 mg subcutaneously, twice daily.

If the patient's health deteriorates under anticoagulant therapy with prophylactic doses (significant increase in the level of D-dimers, tendency to thrombocytopenia), the suspicion of DVT, PE or DIC arises. In this situation, the decision to anticoagulate at therapeutic doses or the change to unfractionated heparin into therapeutic doses will be discussed, in consultation with colleagues from intensive care units (ICU), haematology and cardiology units.

In patients with a history of heparin-induced thrombocytopenia, fondaparinux (arixtra) - 2.5 mg once a day, subcutaneously, is recommended.

Mechanical thromboprophylaxis is recommended in patients with anticoagulation issues.

The use of oral anticoagulants (particularly DOAC - direct oral anticoagulants) is not recommended due to possible interactions with other medicinal products administered to the patient with COVID-19, their presence in the current treatment of COVID-19 patients requiring switching to a curative dose for parenteral anticoagulation (LMWH or UFH).

4. Prophylactic anticoagulation in outpatients

It is recommended to continue prophylactic anticoagulation in all patients with COVID-19 and increased risk of VTE: discharge from intensive care, limited mobilization, history of VTE, active cancer, obesity, thrombophilia, elevated D-dimers.

LMWH or rivaroxaban 10 mg may be administered per os (p.o.) daily for 39 to 45 days. In all cases, the risk of bleeding will be considered.

5. DIC/PE/TVP management

The treatment of these complications will be performed in collaboration with specialists from the cardiology and intensive care units.

An interesting feature of the DIC, which complicates the course of patients with COVID-19, is that bleeding occurs rarely, although coagulation disorders are severe. In order to avoid thrombotic complications (which are much more common), it is recommended that replacement therapy (ME, PPC, platelet preparations) be thoroughly individualised. This substitution therapy should not be given according to coagulation test results alone, but only to patients with active bleeding, an increased risk of bleeding or to those who are going to undergo procedures involving the risk of bleeding.

The role of the tranexamic acid is unknown and its use is not recommended.

We must keep in mind that there are no randomized studies that provide highly recommended information and that our COVID-19 knowledge and management are rapidly evolving.

IV. Antibiotics and other anti-infectives (except for those specific to COVID-19)

The administration of antibiotics and, more broadly, anti-infectives in patients with COVID-19 aims to:

- treat initial COVID-19 associated infections;

- treat infections associated with medical care, more frequently respiratory infections, and with other localisations as well: of soft parts, systemic infections, including cases of sepsis and septic shock;

- a special situation of infections associated with medical care is the reactivation of latent infections in patients receiving immunosuppressive treatment (tuberculosis, herpes infections, pneumocystosis).

During the first period of the disease, the patient with COVID-19 may have concomitant bacterial infections, usually respiratory, which may generate productive cough, increased or increasing serum procalcitonin, leukocytosis with neutrophilia, radiological appearance of alveolar lung opacity, D-dimers > 1 μg/ml. The risk of concomitant bacterial infections appears to be significantly lower than in patients with influenza. A bacteriological screening with testing for the presence in the urine of pneumococcal or Legionella antigens, serologies for atypical bacteria, blood cultures is useful. The antibiotics recommended in early installed pneumonia are those recommended for community forms: amoxicillin clavulanate 1.2 g i.v. every 8 hours + doxycycline 100 mg every 12 hours or moxifloxacin 400 mg / day (for pregnant women: ceftriaxone + azithromycin); the duration of administration will not exceed 5-7 days. Doxycycline has been assigned an additional favourable role as a possible IL-6 inhibitor. Fluoroquinolone should be avoided in patients with rhythm or conduction disorders. Although Gautret reports the efficacy of azithromycin in combination with hydroxychloroquine, an analysis performed for only six cases cannot support the inclusion of this antibiotic in the standard treatment of COVID-19 and / or bacterial infections in conditions of frequent resistance of pneumococci to macrolides in Romania. A study by Gautret and colleagues in a group of 1,064 patients with hydroxychloroquine and azithromycin showed no side effects, favourable clinical outcome and viral clearance in 91% of cases in 10 days.

The occurrence of mechanical ventilation-associated pneumonia was rare in patients with COVID-19, even though the mean duration of ventilation was approximately 3 weeks; in an analysis of 150 cases treated in Wuhan, bacterial superinfection was recorded in 1% of those who survived and in 16% of those who died. In case of pneumonia associated with mechanical ventilation, a treatment scheme adapted to the microbial circulation from the respective intensive care unit will be used. In a meta-analysis, Lippi M. shows that serum procalcitonin levels above 0.5 ng/ml are correlated with an increased risk of adverse outcome.

Following administration of immunosuppressive medicinal products to control the cytokine release syndrome (CRS) (e.g. tocilizumab, baricitinib, anakinra), the patient should be monitored for the risk of breakthrough infections, reactivation of latent tuberculosis, reactivation of herpes infections, or pneumocystosis; in order to be able to evaluate these risks as accurately as possible, we recommend, along with the medical history, the collection and storage of a blood sample prior to the first administration of immunosuppressant, from which serological tests (HSV), Quantiferon TB-Gold and other tests can be performed.

To conclude, the administration of anti-infective medication, other than anti-COVID-19 medication, is indicated in restricted and well-defined categories of patients with this syndrome. The correct use of medical history, physical examination data, biological tests (primarily procalcitonin and complete blood count), imaging examinations and microbiological tests (blood cultures, other examinations) may allow the judicious use of antibiotics required in order to solve the infectious problems associated with COVID- 19. Given the relative rarity of infections associated with this syndrome, the current situation may have a favourable unintended consequence, namely limitation of the selection pressure of antibiotic-resistant microorganisms and restriction of the circulation of these microorganisms.

V. Support of vital functions

Care of patients with severe and critical forms of COVID-19 will be provided by intensive care physicians. Although several syndromes have been described in the months leading to the onset of the pandemic, which may jeopardize the prognosis of the patient with COVID-19 (haemodynamic dysfunction, acute renal failure, severe bacterial breakthrough infections), the main life-threatening condition is the severe respiratory distress and therefore, special attention should be paid to the monitoring of respiratory function in COVID-19 patients. The decrease in O2 saturation to 92% in the atmospheric air in patients at rest, without previous respiratory distress, requires rapid evaluation of arterial gasometry and the enrichment of inspired air with oxygen; additional measures to reduce hypoxemia are decided by the intensive care physician. The aim is to avoid aggravation of tissue hypoxia without resorting as much as possible to more invasive interventions such as mechanical ventilation with IoT or extracorporeal oxygenation. Among the possible methods of intervention, it should be noted that the non-invasive ventilation is a procedure that involves a high risk of aerosolization of SARS-CoV-2, particularly in the mask ventilation variant.

The elements of detail in this regard go beyond the scope of this therapeutic protocol.

VI. Other therapeutic measures may be useful in most cases:

- fighting fever (acetaminophen), myalgias;
- fighting insomnia;
- limiting anxiety to improve the overall condition - lorazepam;
- combating nausea, vomiting - metoclopramide, ondasetron, dexamethasone;
- in patients with viscous respiratory secretions - in COVID-19 or a bacterial breakthrough infection - the fluidification of secretions can be resorted to by nebulisations with acetylcysteine and beta-mimetics or with hypertonic and beta-mimetic solution;
- the prophylaxis of bedsores in the immobilised / severe patient requires the change of position every two hours;
- prophylaxis of stress ulcer by gastric antisecretory medicinal products and rapid resumption of enteral nutrition;
- there is a risk of potentiation of activity between statins and ritonavir-associated protease inhibitors; therefore it is proposed to limit the dose of atorvastatin to 20 mg / day;
- *In forms with significant inflammation and / or hypoxemia in diabetic patients, the risk of ketoacidosis is higher and correction with fast-acting insulin is recommended.*

Controversial or seemingly unnecessary therapeutic interventions

• Although the need to replace ACE inhibitors and / or sartans in the treatment of patients diagnosed with COVID-19, if previously received, was discussed, the European Society of Cardiology group - the group for hypertension issued on 13 March 2020 a recommendation for these medicinal products to be maintained in treatment regimens; a similar recommendation was issued in the USA on 17 March 2020 by the American Cardiology Association.

• There is a reluctance to use NSAIDs in the treatment of COVID-19 that has been widely disseminated in France since March 2020, related to the inhibition of the beneficial effect of inflammation in cases of low-medium severity COVID-19. There is no clinical data to support this claim; however, it is reasonable to assume that the adverse effects of NSAIDs in COVID-19, such as renal or related to the digestive tract, are more common.

• The following are considered unnecessary or even harmful: intravenous immunoglobulins, volume recovery with colloidal solutions (debatable for albumin).

Proposed treatment depending on the severity of the case and the risk factors for severe evolution

Form of disease (severity)	*Recommended treatment*	*Dose/day*	*Standard duration of treatment*	*Adverse reactions*
Asymptomatic	*No*			
Mild *- acute upper respiratory tract infections (RTIs)*	*hydroxychloroquine**	*2 x 400 mg/day on the first day (2 x 2 tb/day), then 2 x 200 mg/day (2 x 1 tb/day) Children 5 mg/kilogram body weight/day, split into two*	*5 - 7 days*	*Rhythm/driving disorders*
	Associated with lopinavir/ritonavir) or*	*2 x 400/100 mg/day (2 x 2 tb/day) Children 2 x 300/75 mg/m2/day*	*7 - 10 days*	*diarrhoea (40.9%), nausea (40.9%), stomatitis (18.2%),*
	*Azithromycin **)*	*500 mg/day, day 1, then 250 mg/day, another 4 days*	*5 days*	*anaemia (45.0%),*
	Umifenovir	*3 x 200 mg/day*	*10 - 14 days*	*leukopenia (40.0%)*
Average *Pneumonia without severity criteria*	*hydroxychloroquine *) + Lopinavir/Ritonavir***) or Azithromycin **) Umifenovir*	*2 x 400 mg/day on the first day (2 x 2 tb/day), then 2 x 200 mg/day (2 x 1 tb/day) Children 5 mg/kilogram body weight/day split into two 2 x 400/100 mg/day Children 2 x 300/75 mg/m2/day 500 mg/day, on day 1, then 250 mg/day, another 4 days 3 x 200 mg/day*	*5 - 7 days 10 - 14 days 5 days 10 - 14 days*	*Administered with food or with a mug of milk*

Severe[a]***/ Critical***[b]	*hydroxychloroquine *)*	*2 x 400 mg/day on the first day, then 2 x 200 mg/day Children 5 mg/kilogram body weight/day split into two*	*minimum 5 days*	*In accordance with the description concerning remdesivir mentioned above*
	+ remdesivir	*200 mg/day on day 1, then 100 mg/day Children sub 40 kg - 5 mg/kilogram body weight/day on day 1, 2.5 mg/kilogram body weight/day thereafter*	*10 days*	
	or Lopinavir/Ritonavir if remdesivir is not available (until it is procured)	*The dose is administered as syrup via nasogastric tube ****).*		
	+ immunomodulatory therapy:			
	*Tocilizumab (in patients with "cytokine storm" symptoms*****)*	*8 mg/kilogram body weight, maximum 800 mg slow endovenous infusion in adults (12 mg/kg in children under 30 kg)*	*1 - 3 doses with at least 8 hours between them*	
	Corticoids, convalescent plasma, other immunosuppressive medicinal products			

**) ECG to be performed daily for QT evaluation; contraindications: QT > 500 msec, myasthenia gravis, porphyria, retinal pathology, epilepsy; benefit-risk analysis for pregnant women; can be replaced with umifenovir, favipiravir, remdesivir (with the restrictions specified in the text).*

***) In patients with corrected QT <500 ms, with daily ECG and ionogram at 48 hours.*

****) Replace lopinavir / ritonavir with umifenovir in combination with hydroxychloroquine in patients with cardiac problems at risk for QT prolongation arrhythmias.*

*****) Lopinavir / ritonavir tablets lose about half of their effectiveness.*

******) Hemophagocytic lymphohistiocytosis. a. Severe = at least one of: respiratory rate ≥ 30 / min (≥ 40 / min in preschoolers); SaO2 ≤ 93%; PaO2 / FiO2 <300; pulmonary infiltrates that increase by more than 50% in 24-48 hours. b. Critical = at least one of: acute respiratory distress; sepsis; altered consciousness; multiple organ failure (MOF).*

The duration of treatment is indicative, it can be prolonged or shortened according to the patient's progress, but without being reduced to less than 5 days (provided that no severe side effects occur).

The patient is monitored clinically and biologically - biochemically daily, in patients with moderate-severe-critical forms; the repetition of imaging and biological tests is mandatory in an emergency in case of clinical aggravation.

Testing for viral RNA in faeces is not justified on the basis of existing data.

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Medicinal product batches recalled during the 1st quarter of 2020

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	Arnetin 50 mg/2 ml	solution for injection	50 mg/ 2 ml	ranitidine	Medochemie LTD, Cyprus	A711AH	voluntary recall from the market, at pharmacy level, **as a precautionary measure**, following identification of an increasing tendency of the level of nitrosamine impurities, throughout performed tests	Voluntary recall and destruction	18.02.2020
2	Indapamid LPH 2.5 mg	film-coated tablets	2.5 mg	indapamid	Labormed Phama SA, Romania	all valid batches (480483, 472287, 473603, 475648, 477462, 482249)	voluntary recall from the market (warehouses and pharmacies), following out-of-specification results for "Dissolution" for batch no. 480483	Voluntary recall and destruction	12.03.2020
3	Emsya 5 mg	tablets	5 mg	ulipristal acetate	Gedeon Richter Plc. Hungary	all batches	voluntary recall from the market (warehouses and pharmacies), following initiation by PRAC-EMA of the EMEA/H/A-31/1496 procedure on review of risk of medicinal products containing ulipristal acetate 5 mg, used in treatment of uterine fibroids	Voluntary recall and destruction	30.03.2020
4	Sevorane 250 ml	volatile liquid for inhalation		sevoflurane	Aesica Queenborough Ltd. Great Britain/ Abbvie Deutschland GmbH, Germany	all batches	voluntary recall from the market (warehouses and pharmacies), following dismission of the medicinal product from CaNaMed and the Public Catalogue starting with 02.11.2019	Voluntary recall and destruction	30.03.2020

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMDR during the 4th quarter of 2019

Therapeutic areas

A01 – STOMATOLOGICAL PREPARATIONS
A02 - DRUGS FOR ACID RELATED DISORDERS
A03 – DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
A05- BILE AND LIVER THERAPY
A06- DRUGS FOR CONSTIPATION
A07 – ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS
A10- DRUGS USED IN DIABETES
B01 - ANTITHROMBOTIC AGENTS
B05 – BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS
C01 – CARDIAC THERAPY
C03 - DIURETICS
C07 – BETA BLOCKING AGENTS
C08 – CALCIUM CHANNEL BLOCKERS
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C10 - LIPID MODIFYING AGENTS
D07 – CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS
G01- GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS
G02 – OTHER GYNECOLOGICALS
G03 - SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
G04 - UROLOGICALS
H05- PARATHYROID HORMONES AND ANALOGUES
J01 - ANTIBACTERIALS FOR SYSTEMIC USE
J02 - ANTIMYCOTICS FOR SYSTEMIC USE
J05 - ANTIVIRALS FOR SYSTEMIC USE
L01 – ANTINEOPLASTIC AGENTS
L02- ANTINEOPLASTICS (HORMONE ANTAGONISTS AND RELATED AGENTS)
L04- IMMUNOSUPPRESSIVE MEDICINAL PRODUCTS
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
N02- ANALGESICS
N04 - ANTI-PARKINSON DRUGS
N05 - PSYCHOLEPTICS
N06 - PSYCHOANALEPTICS
N07- DRUGS USED IN NICOTINE DEPENDENCE
R01 - NASAL PREPARATIONS
R02 - THROAT PREPARATIONS
R03 - DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
R05 - COUGH AND COLD PREPARATIONS

R06 - ANTIHISTAMINES FOR SYSTEMIC USE
R07- OTHER RESPIRATORY SYSTEM PRODUCTS
S01 - OPHTHALMOLOGICALS
V01- ALLERGENS
V03 – ALL OTHER THERAPEUTIC PRODUCTS

Medicinal products authorised for marketing during the 4th quarter of 2019

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
ABACAVIRUM/ LAMIVUDINUM	ABACAVIR/LAMIVUDINA STADA	film-coated tablets	600mg/ 300mg	STADA M&D SRL	ROMANIA	12799	2019	01
ACETATUM DE FLECAINIDUM	TAMBOCOR	tablets	50 mg	MYLAN S.A.S.	IRELAND	12759	2019	01
ACETATUM DE FLECAINIDUM	TAMBOCOR	tablets	100 mg	MYLAN S.A.S.	IRELAND	12760	2019	01
ACETYLCYSTEINUM	MUCOVIM 200 mg	capsules	200 mg	VIM SPECTRUM S.R.L.	ROMANIA	12878	2019	01
ACETYLSALICYLIC ACID/ PSEUDOEPHEDRINE HYDROCLORIDE	ASPIRIN COMPLEX	effervescent granules for oral solution	500mg/30mg	BAYER S.R.L.	ROMANIA	12605	2019	01
ACIDUM ACETYLSALICYLICUM	SANTEPIRIN	gastro-resistant tablets	75mg	LAROPHARM S.R.L.	ROMANIA	12643	2019	01
ACIDUM ACETYLSALICYLICUM	ASPIMAX CARDIO	gastro-resistant tablets	75 mg	LAROPHARM S.R.L.	ROMANIA	12787	2019	01
ACIDUM ACETYLSALICYLICUM	PROTECARDIN	gastro-resistant tablets	75mg	BIOFARM S.A.	ROMANIA	12832	2019	01
ACIDUM ACETYLSALICYLICUM	ASAPRIN TAMPONAT	tablets	500mg	AC HELCOR PHARMA SRL	ROMANIA	12838	2019	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC LABORMED	tablets	500mg	LABORMED PHARMA S.A.	ROMANIA	12804	2019	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC TAMPONAT SOLACIUM	tablets	500mg	SOLACIUM PHARMA	ROMANIA	12883	2019	01
ACIDUM ASCORBICUM	VITAMINA C-RICHTER	film-coated tablets	500mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	12585	2019	01

ACIDUM URSODEOXYCHOLICUM	ACID URSODEOXICOLIC POLISANO	capsules	250 mg	POLIPHARMA INDUSTRIES	ROMANIA	12740	2019	01
ALPROSTADILUM	VITAROS	cream	2mg/g	RECORDATI IRELAND LTD.	IRELAND	12797	2019	01
ALPROSTADILUM	VITAROS	cream	3mg/g	RECORDATI IRELAND LTD.	IRELAND	12798	2019	01
ALUMINIUM HYDROXIDUM + MAGNESIUM HYDROXIDUM	DICARBOCALM N	chewable tablets	306 mg + 400 mg	ZENTIVA a.s.	SLOVENIA	12691	2019	01
AMINOPHYLINUM	AMINOFILINA ARENA	tablets	200mg	ARENA GROUP S.A.	ROMANIA	12764	2019	01
AMINOPHYLINUM	AMINOFILINA ARENA	tablets	100mg	ARENA GROUP S.A.	ROMANIA	12763	2019	01
AMLODIPINUM BESYLATE	AMLODIPINA ARENA	tablets	5 mg	ARENA GROUP S.A.	ROMANIA	12580	2019	01
AMLODIPINUM BESYLATE	AMLODIPINA ARENA	tablets	10 mg	ARENA GROUP S.A.	ROMANIA	12581	2019	01
AMOXICILINUM	OSPAMOX	film-coated tablets	500mg	SANDOZ GmbH	AUSTRIA	12789	2019	01
AMOXICILINUM	OSPAMOX	film-coated tablets	1000mg	SANDOZ GmbH	AUSTRIA	12790	2019	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	ENHANCIN	film-coated tablets	625mg	TERAPIA S.A	ROMANIA	12550	2019	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOKSIKLAV 312.5mg/5 ml	powder for oral suspension	312.5mg/5ml	LEK PHARMACEUTICALS d.d.	SLOVENIA	12757	2019	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOKSIKLAV 156.25mg/5ml	powder for oral suspension	156.25 mg/ 5ml	LEK PHARMACEUTICALS d.d.	SLOVENIA	12756	2019	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	ENHANCIN	film-coated tablets	875/125mg	TERAPIA S.A	IRELAND	12777	2019	01
AMPICILLINUM	EPICOCILLIN 250 mg	powder for solution for injection	250 mg	EIPICO MED SRL	ROMANIA	12672	2019	01
AMPICILLINUM	EPICOCILLIN 1g	powder for solution for injection/infusion	1g	EIPICO MED SRL	ROMANIA	12673	2019	01

ANASTRAZOLUM	KYARESTA	film-coated tablets	1mg	NEOLA PHARMA SRL	ROMANIA	12683	2019	01
ANIDULAFUNGINUM	ANIDULAFUNGINA FRESENIUS KABI	powder for concentrate for solution for infusion	100mg	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	12738	2019	01
ARIPIPRAZOLUM	ARIPIPRAZOL AUROBINDO	tablets	10mg	AUROBINDO PHARMA LIMITED	MALTA	12819	2019	01
ARIPIPRAZOLUM	ARIPIPRAZOL AUROBINDO	tablets	15mg	AUROBINDO PHARMA LIMITED	MALTA	12820	2019	01
ATORVASTATINUM	ATORVASTATINA MSN	film-coated tablets	10mg	VIVANTA GENERICS sro	THE CZECH REPUBLIC	12792	2019	01
ATORVASTATINUM	ATORVASTATINA MSN	film-coated tablets	20mg	VIVANTA GENERICS sro	THE CZECH REPUBLIC	12793	2019	01
ATORVASTATINUM	ATORVASTATINA MSN	film-coated tablets	40mg	VIVANTA GENERICS sro	THE CZECH REPUBLIC	12794	2019	01
ATORVASTATINUM	ATORVASTATINA MSN	film-coated tablets	80mg	VIVANTA GENERICS sro	THE CZECH REPUBLIC	12795	2019	01
AZITHROMYCINUM	AZITROMICINA ARENA	film-coated tablets	500mg	ARENA GROUP S.A.	ROMANIA	12791	2019	01
BECLOMETASONUM DIPROPIONATE	SOPROBEC	pressurised solution for inhalation	50mcg	GLENMARK GENERICS EUROPE LTD.	UK	12843	2019	01
BECLOMETASONUM DIPROPIONATE	SOPROBEC	pressurised solution for inhalation	100mcg	GLENMARK GENERICS EUROPE LTD.	UK	12844	2019	01
BECLOMETASONUM DIPROPIONATE	SOPROBEC	pressurised solution for inhalation	200mcg	GLENMARK GENERICS EUROPE LTD.	UK	12845	2019	01
BECLOMETASONUM DIPROPIONATE	SOPROBEC	pressurised solution for inhalation	250mcg	GLENMARK GENERICS EUROPE LTD.	UK	12846	2019	01

BENDAMUSTINUM	BENMAK	powder for concentrate for solution for infusion/injection	2.5 mg/ml	SYNTHON BV	HOLLAND	12827	2019	01
BENFOTIAMINUM	TIAVELLA	film-coated tablets	50mg	G.L. PHARMA GmbH	AUSTRIA	12775	2019	01
BENFOTIAMINUM	TIAVELLA	film-coated tablets	300mg	G.L. PHARMA GmbH	AUSTRIA	12776	2019	01
BENZIDAMINUM HYDROCHLORIDE	GARGANTA	oromucosal spray, solution	1.5mg/ml	PHARMASWISS CESKA REPUBLIKA s.r.o.	THE CZECH REPUBLIC	12824	2019	01
BENZIDAMINUM HYDROCHLORIDE	GARGANTA	orodispersible tablets	3mg	PHARMASWISS CESKA REPUBLIKA s.r.o.	THE CZECH REPUBLIC	12823	2019	01
BETAHISTINUM DIHYDROCHLORIDE	BETASERC	orodispersible tablets	24mg	MYLAN HEALTHARE GMBH	IRELAND	12796	2019	01
BISACODILUM	BISACODIL SINTOFARM	suppositories	10mg	SINTOFARM S.A.	ROMANIA	12640	2019	01
BISOPROLOLUM /AMLOPIDINUM	SOBYCOMBI	tablets	5mg/5mg	KRKA D.D. NOVO MESTO	SLOVENIA	12717	2019	01
BISOPROLOLUM /AMLOPIDINUM	SOBYCOMBI	tablets	5mg/10mg	KRKA D.D. NOVO MESTO	SLOVENIA	12718	2019	01
BISOPROLOLUM /AMLOPIDINUM	SOBYCOMBI	tablets	10mg/5mg	KRKA D.D. NOVO MESTO	SLOVENIA	12719	2019	01
BISOPROLOLUM /AMLOPIDINUM	SOBYCOMBI	tablets	10mg/10mg	KRKA D.D. NOVO MESTO	SLOVENIA	12720	2019	01
BORTEZOMIBUM	BORTEZOMIB MYLAN	powder for solution for injection	1 mg	MYLAN S.A.S.	FRANCE	12721	2019	01
BORTEZOMIBUM	BORTEZOMIB MYLAN	powder for solution for injection	3.5mg	MYLAN S.A.S.	FRANCE	12722	2019	01
BROMHEXINUM HYDROCHLORIDE	BROMFLUEX	tablets	8 mg	BIO EEL SRL	ROMANIA	12551	2019	01

BUSPIRONE HYDROCLORIDE	SPITOMIN	tablets	5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	12676	2019	01
BUSPIRONE HYDROCLORIDE	SPITOMIN	tablets	10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	12677	2019	01
CANDESARTANUM CILEXETIL	CANDESARTAN CILEXETIL MCC	tablets	8mg	MAGISTRA C&C S.R.L.	ROMANIA	12710	2019	01
CANDESARTANUM CILEXETIL + HYDROCHLOROTHIAZIDUM	CANDESARTAN /HIDROCLOROTIAZIDA AUROBINDO	tablets	8mg/12.5mg	AUROBINDO PHARMA LIMITED	ROMANIA	12854	2019	01
CANDESARTANUM CILEXETIL + HYDROCHLOROTHIAZIDUM	CANDESARTAN /HIDROCLOROTIAZIDA AUROBINDO	tablets	16mg/12.5mg	AUROBINDO PHARMA LIMITED	ROMANIA	12855	2019	01
CANDESARTANUM CILEXETIL + HYDROCHLOROTHIAZIDUM	CANDESARTAN /HIDROCLOROTIAZIDA AUROBINDO	tablets	32mg/12.5mg	AUROBINDO PHARMA LIMITED	ROMANIA	12856	2019	01
CANDESARTANUM CILEXETIL + HYDROCHLOROTHIAZIDUM	CANDESARTAN /HIDROCLOROTIAZIDA AUROBINDO	tablets	32mg/25mg	AUROBINDO PHARMA LIMITED	ROMANIA	12857	2019	01
CANDESARTANUM/ AMLODIPINUM BESYLATE	CARAMLO	tablets	16mg/5mg	ZENTIVA k.s.	THE CZECH REPUBLIC	12557	2019	01
CARBAMAZEPINUM	CARBEPSIL	tablets	200mg	AC HELCOR PHARMA SRL	ROMANIA	12641	2019	01
CARBAMAZEPINUM	CARBEPSIL	tablets	400mg	AC HELCOR PHARMA SRL	ROMANIA	12642	2019	01
CEFIXIMUM	EFICEF	capsules	100mg	ANTIBIOTICE S.A.	ROMANIA	12615	2019	01

CEFOPERAZONUM	CEFOZON	powder for solution for injection/infusion	500 mg	E.I.P.I.C.O. MED S.R.L.	ROMANIA	12678	2019	01
CEFOPERAZONUM	CEFOZON	powder for solution for injection/infusion	2 g	E.I.P.I.C.O. MED S.R.L.	ROMANIA	12680	2019	01
CEFOPERAZONUM	CEFOZON	powder for solution for injection/infusion	1 g	E.I.P.I.C.O. MED S.R.L.	ROMANIA	12679	2019	01
CEFTRIAXONUM	MEDAXONE	powder for solution for injection/infusion	500mg	MEDOCHEMIE LTD	CYPRUS	12840	2019	01
CEFTRIAXONUM	SEFTRION	powder for solution for injection/infusion	2g	E.I.P.I.C.O. MED S.R.L.	ROMANIA	12880	2019	01
CIPROFLOXACINUM	CUMINOL	film-coated tablets	500 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	12751	2019	01
CIPROFLOXACINUM	CUMINOL	film-coated tablets	250 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	12750	2019	01
CIPROFLOXACINUM HYDROCHLORIDE	CIPROFLOXACINA AUROBINDO	film-coated tablets	250mg	AUROBINDO PHARMA LIMITED	INDIA	12847	2019	01
CIPROFLOXACINUM HYDROCHLORIDE	CIPROFLOXACINA AUROBINDO	film-coated tablets	500mg	AUROBINDO PHARMA LIMITED	INDIA	12848	2019	01
CIPROFLOXACINUM HYDROCHLORIDE	CIPROFLOXACINA AUROBINDO	film-coated tablets	750mg	AUROBINDO PHARMA LIMITED	INDIA	12849	2019	01
CITALOPRAMUM HYDROBROMIDE	LINISAN	tablets	20mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	12839	2019	01
CLOFARABINUM	CLOFARABINA ACCORD	concentrate for solution for injection	1mg/ml	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	12596	2019	01
CLOFARABINUM	CLOFARABINA KOANAA	concentrate for solution for infusion	1mg/ml	KOANAA HEALTHCARE GMBH	AUSTRIA	12620	2019	01

CLORHIDRAT DE TRAMADOLUM	CLORHIDRAT DE TRAMADOL BIOEEL	tablets	50 mg	BIO EEL SRL	ROMANIA	12837	2019	01
CLOTRIMAZOLUM	CLOTRIMAZOL HYPERION	cream	10 mg/g	HYPERION S.A.	ROMANIA	12811	2019	01
COMBINATIONS	NUROFEN PLUS	tablets		RECKITT BENCKISER HEALTHCARE LTD	UK	12573	2019	01
COMBINATIONS	ANTINEVRALGIC SINUS	film-coated tablets		SANOFI ROMANIA SRL	ROMANIA	12597	2019	01
COMBINATIONS	ROXAMPEX	film-coated tablets	10mg/5mg/ 4mg	KRKA D.D. NOVO MESTO	SLOVENIA	12656	2019	01
COMBINATIONS	ROXAMPEX	film-coated tablets	10mg/5mg/ 8mg	KRKA D.D. NOVO MESTO	SLOVENIA	12657	2019	01
COMBINATIONS	ROXAMPEX	film-coated tablets	10mg/10mg/ 8mg	KRKA D.D. NOVO MESTO	SLOVENIA	12658	2019	01
COMBINATIONS	ROXAMPEX	film-coated tablets	20mg/5mg/ 4mg	KRKA D.D. NOVO MESTO	SLOVENIA	12659	2019	01
COMBINATIONS	ROXAMPEX	film-coated tablets	20mg/5mg/ 8mg	KRKA D.D. NOVO MESTO	SLOVENIA	12660	2019	01
COMBINATIONS	ROXAMPEX	film-coated tablets	20mg/10mg/ 8mg	KRKA D.D. NOVO MESTO	SLOVENIA	12661	2019	01
COMBINATIONS	CAFFETIN COLD PLUS	film-coated tablets		INN-FARM d.o.o.	SLOVENIA	12697	2019	01
COMBINATIONS	BETABIOPTAL	eye ointment		THEA FARMA S.p.A.	ITALY	12727	2019	01
COMBINATIONS	CAFFETIN	tablets		ALKALOID-INT	SLOVENIA	12726	2019	01
COMBINATIONS	PARASINUS	tablets		EUROPHARM S.A.	ROMANIA	12755	2019	01
COMBINATIONS	CERNEVIT	lyophilisate for solution for injection/infusion		BAXTER AG	ROMANIA	12784	2019	01
COMBINATIONS	TRI-REGOL	coated tablets		GEDEON RICHTER PLC	HUNGARY	12879	2019	01

DARUVAVIRUM PROPYLENE GLYCOLATUM	DARUNAVIR GLENMARK	film-coated tablets	400mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	12711	2019	01
DARUVAVIRUM PROPYLENE GLYCOLATUM	DARUNAVIR GLENMARK	film-coated tablets	600mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	12712	2019	01
DARUVAVIRUM PROPYLENE GLYCOLATUM	DARUNAVIR GLENMARK	film-coated tablets	800mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	12713	2019	01
DASATINIBUM	DASATINIB ZENTIVA	film-coated tablets	20mg	ZENTIVA k.s.	THE CZECH REPUBLIC	12591	2019	01
DASATINIBUM	DASATINIB ZENTIVA	film-coated tablets	50mg	ZENTIVA k.s.	THE CZECH REPUBLIC	12592	2019	01
DASATINIBUM	DASATINIB ZENTIVA	film-coated tablets	70mg	ZENTIVA k.s.	THE CZECH REPUBLIC	12593	2019	01
DASATINIBUM	DASATINIB ZENTIVA	film-coated tablets	100mg	ZENTIVA k.s.	THE CZECH REPUBLIC	12594	2019	01
DASATINIBUM	DASATINIB MYLAN	film-coated tablets	20mg	MYLAN S.A.S.	IRELAND	12607	2019	01
DASATINIBUM	DASATINIB MYLAN	film-coated tablets	50mg	MYLAN S.A.S.	IRELAND	12608	2019	01
DASATINIBUM	DASATINIB MYLAN	film-coated tablets	70mg	MYLAN S.A.S.	IRELAND	12609	2019	01
DASATINIBUM	DASATINIB MYLAN	film-coated tablets	80mg	MYLAN S.A.S.	IRELAND	12610	2019	01
DASATINIBUM	DASATINIB MYLAN	film-coated tablets	100mg	MYLAN S.A.S.	IRELAND	12611	2019	01
DASATINIBUM	DASATINIB MYLAN	film-coated tablets	140mg	MYLAN S.A.S.	IRELAND	12612	2019	01
DASATINIBUM	DASATINIB KRKA	film-coated tablets	20mg	KRKA D.D. NOVO MESTO	SLOVENIA	12650	2019	01
DASATINIBUM	DASATINIB KRKA	film-coated tablets	50mg	KRKA D.D. NOVO MESTO	SLOVENIA	12651	2019	01

DASATINIBUM	DASATINIB KRKA	film-coated tablets	70mg	KRKA D.D. NOVO MESTO	SLOVENIA	12652	2019	01
DASATINIBUM	DASATINIB KRKA	film-coated tablets	80mg	KRKA D.D. NOVO MESTO	SLOVENIA	12653	2019	01
DASATINIBUM	DASATINIB KRKA	film-coated tablets	100 mg	KRKA D.D. NOVO MESTO	SLOVENIA	12654	2019	01
DASATINIBUM	DASATINIB KRKA	film-coated tablets	140mg	KRKA D.D. NOVO MESTO	SLOVENIA	12655	2019	01
DASATINIBUM	DASATINIB ALVOGEN	film-coated tablets	20mg	ALVOGEN PHARMA TRADING EUROPE EOOD	BULGARIA	12812	2019	01
DASATINIBUM	DASATINIB ALVOGEN	film-coated tablets	50mg	ALVOGEN PHARMA TRADING EUROPE EOOD	BULGARIA	12813	2019	01
DASATINIBUM	DASATINIB ALVOGEN	film-coated tablets	70mg	ALVOGEN PHARMA TRADING EUROPE EOOD	BULGARIA	12814	2019	01
DASATINIBUM	DASATINIB ALVOGEN	film-coated tablets	80mg	ALVOGEN PHARMA TRADING EUROPE EOOD	BULGARIA	12815	2019	01
DASATINIBUM	DASATINIB ALVOGEN	film-coated tablets	100mg	ALVOGEN PHARMA TRADING EUROPE EOOD	BULGARIA	12816	2019	01
DASATINIBUM	DASATINIB ALVOGEN	film-coated tablets	140mg	ALVOGEN PHARMA TRADING EUROPE EOOD	BULGARIA	12817	2019	01
DEXAMETHASONUM PHOSPHATE	DEXAMETAZONA FOSFAT DE SODIU NEWLINE PHARMA	eye drops, solution	1.5mg/ml	NEW LINE PHARMA	SPAIN	12709	2019	01

DEXMEDETOMIDUM	DEXMEDETOMIDINA KALCEKS 100 mcg	concentrate for solution for injection	100 mcg	AS KALCEKS	LATVIA	12626	2019	01
DICLOFENACUM SODIUM	DICLOFENAC MCC	cream	10mg/g	MAGISTRA C&C	ROMANIA	12687	2019	01
DICLOFENACUM SODIUM + HEPARIN SODIUM	ALLE FORTE	cream	10 mg + 1000 IU/g	FITERMAN PHARMA SRL	ROMANIA	12554	2019	01
DICLOFENACUM SODIUM +HEPARIN SODIUM	ALLE	cream	10 mg + 250 IU/gram	FITERMAN PHARMA SRL	ROMANIA	12553	2019	01
DICLOFENACUM SODIUM +HEPARIN SODIUM	ALLE	gel	10mg + 500 IU/g	FITERMAN PHARMA SRL	ROMANIA	12552	2019	01
DIGOXINUM	DIGOXIN ZENTIVA	tablets	0.25mg	ZENTIVA S.A.	ROMANIA	12803	2019	01
DROTAVERINUM HYDROCHLORIDE	ANTISPASMIN FORTE	tablets	80mg	BIOFARM S.A.	ROMANIA	12725	2019	01
DULOXETINUM	DUTILOX	gastro-resistant capsules	30mg	DISTRIQUIMICA SA	SPAIN	12601	2019	01
DULOXETINUM	DUTILOX	gastro-resistant capsules	60mg	DISTRIQUIMICA SA	SPAIN	12602	2019	01
DUTASTERIDUM/ TAMSULOSINUM	DUSTIN DUO	capsules	0.5mg/0.4mg	MYLAN S.A.S.	IRELAND	12538	2019	01
DUTASTERIDUM/ TAMSULOSINUM	DUTASTERIDA/ TAMSULOSIN ACCORD	cps	0.5mg/0.4mg	SAG MANUFACTURING S.L.U.	SPAIN	12560	2019	01
DUTASTERIDUM/ TAMSULOSINUM	EXIFINE	capsules	0.5mg/0.4mg	DR. REDDY'S LABORATORIES	ROMANIA	12598	2019	01
DUTASTERIDUM/ TAMSULOSINUM	DUTASTERIDA/ TAMSULOSIN STADA	capsules	0.5mg/0.4mg	STADA M&D SRL	ROMANIA	12623	2019	01
DUTASTERIDUM/ TAMSULOSINUM	DYVIXAREZ	capsules	0.5mg/0.4mg	YES GMBH	GERMANY	12818	2019	01
DUTASTERIDUM/ TAMSULOSINUM	TWINPROS	capsules	0.5mg/0.4mg	KRKA D.D. NOVO MESTO	SLOVENIA	12851	2019	01

ENALAPRILUM MALEATE	ENALAPRIL LAROPHARM	tablets	20mg	LAROPHARM S.R.L.	ROMANIA	12638	2019	01
ENALAPRILUM MALEATE	ENALAPRIL LAROPHARM	tablets	5mg	LAROPHARM S.R.L.	ROMANIA	12636	2019	01
ENALAPRILUM MALEATE	ENALAPRIL LAROPHARM	tablets	10mg	LAROPHARM S.R.L.	ROMANIA	12637	2019	01
ESCITALOPRAMUM	ESCITALOPRAM ACTAVIS	film-coated tablets	20mg	ACTAVIS GROUP PTC	ICELAND	12771	2019	01
ESCITALOPRAMUM	ESCITALOPRAM ACTAVIS	film-coated tablets	10mg	ACTAVIS GROUP PTC	ICELAND	12770	2019	01
ESCITALOPRAMUM OXALATE	ESCITALOPRAM ATB	film-coated tablets	10mg	ANTIBIOTICE S.A.	ROMANIA	12532	2019	01
ESCITALOPRAMUM OXALATE	ESCITALOPRAM ATB	film-coated tablets	20mg	ANTIBIOTICE S.A.	ROMANIA	12533	2019	01
ESCITALOPRAMUM OXALATE	ELICEA Q-TAB	orodispersible tablets	5mg	KRKA D.D. NOVO MESTO	SLOVENIA	12765	2019	01
ESCITALOPRAMUM OXALATE	ELICEA Q-TAB	orodispersible tablets	10mg	KRKA D.D. NOVO MESTO	SLOVENIA	12766	2019	01
ESCITALOPRAMUM OXALATE	ELICEA Q-TAB	orodispersible tablets	15mg	KRKA D.D. NOVO MESTO	SLOVENIA	12767	2019	01
ESCITALOPRAMUM OXALATE	ELICEA Q-TAB	orodispersible tablets	20mg	KRKA D.D. NOVO MESTO	SLOVENIA	12768	2019	01
ETAMBUTOLUM	CLORHIDRAT DE ETAMBUTOL ARENA	capsules	400mg	ARENA GROUP S.A.	ROMANIA	12877	2019	01
ETHINILESTRADIOLUM/CIPROTERONUM ACETATE	DIANE 35	coated tablets	0.035mg/2 mg	BAYER AG	GERMANY	12690	2019	01
ETHINYLESTRADIOL + CLORMADINONE ACETATE	BELARA CONTINU	film-coated tablets	0.03 mg/2 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	12587	2019	01
ETONOGESTREL + ETHINYLESTRADIOL	PERLINRING	vaginal delivery system	0.120 mg/ 0.015 mg/ 24 hours	ACTAVIS GROUP PTC EHF	ICELAND	12540	2019	01
EVEROLIMUS	VERIMMUS	tablets	5mg	EGIS PHARMACEUTICALS PLC	HOLLAND	12555	2019	01

EVEROLIMUS	VERIMMUS	tablets	10mg	EGIS PHARMACEUTICALS PLC	HOLLAND	12556	2019	01
DRY IVY LEAF EXTRACT	MUCOLANT IEDERA	syrup	1.54mg/ml	DR THEISS NATURWAREN GMBH	GERMANY	12739	2019	01
EZETIMIBUM	EZETIMIBE URIACH	tablets	10mg	J URI8ACH COMPANIA SA	SPAIN	12853	2019	01
FENOBARBITALUM	FENOBARBITAL ZENTIVA	tablets	100 mg	ZENTIVA S.A.	ROMANIA	12833	2019	01
FENOBARBITALUM	FENOBARBITAL ZENTIVA	solution for injection	100 mg/ml	ZENTIVA S.A.	ROMANIA	12810	2019	01
FLUCONAZOLUM	FLUCONAZOL INFOMED	solution for infusion	2mg/ml	INFOMED FLUIDS S.R.L.	ROMANIA	12578	2019	01
FLUCONAZOLUM	FLUCONAZOL LPH	capsules	50mg	LABORMED PHARMA S.A.	ROMANIA	12616	2019	01
FLUCONAZOLUM	FLUCONAZOL LPH	capsules	150mg	LABORMED PHARMA S.A.	ROMANIA	12617	2019	01
FLUCONAZOLUM	FLUCONAZOL Arena	capsules	50 mg	ARENA GROUP S.A.	ROMANIA	12785	2019	01
FLUCONAZOLUM	FLUCONAZOL Arena	capsules	150 mg	ARENA GROUP S.A.	ROMANIA	12786	2019	01
FLUCONAZOLUM	FLUCONAZOL ZENTIVA	capsules	150 mg	ZENTIVA k.s.	THE CZECH REPUBLIC	12884	2019	01
FLUOROURACILUM	FLUOROURACIL ACCORD	solution for injection/infusion	50mg/ml	ACCORD HEALTHCARE LIMITED	UK	12866	2019	01
FLUOXETINUM HYDROCHLORIDE	FLUOXETINA ARENA	capsules	10 mg	ARENA GROUP S.A.	ROMANIA	12874	2019	01
FLUOXETINUM HYDROCHLORIDE	FLUOXETINA ARENA	capsules	20 mg	ARENA GROUP S.A.	ROMANIA	12875	2019	01
FOSFAMYCINUM TROMETAMOL	FOSFOMICINA ROMPHARM	granules for oral solution	3 g	ROMPHARM COMPANY S.R.L.	ROMANIA	12870	2019	01

FOSFAT SODIC DE BATAMETAZONA/ CLORAMFENICOL	BETABIOPTAL	eye gel	1.3 mg/g+ 2.5mg/g	THEA FARMA S.p.A.	ITALY	12728	2019	01
FOSFOMYCINUM	FOMICYT	powder for solution for infusion	40mg/ml	INFECTOPHARM ARZNEIMITTEL GMBH	GERMANY	12749	2019	01
FOTEMUSTINUM	MUSTOPHORAN	lyophilisate and solvent for solution for infusion	208 mg	LES LAB. SERVIER	FRANCE	12574	2019	01
GEMCITABINUM HYDROCHLORIDE	GEMCITABINA KABI	concentrate for solution for infusion	38mg//ml	FRESENIUS KABI ONCOLOGY PLC	UK	12559	2019	01
GINKGO BILOBA	GINKGO BILOBA BIOFARM	film-coated tablets	80mg	BIOFARM S.A.	ROMANIA	12575	2019	01
GLATIRAMERUM ACETATE	COPAXONE	solution for injection (pre-filled syringes)	40mg/ml	TEVA PHARMACEUTICAL WORKS LTD	UK	12772	2019	01
GLIPIZIDUM	GLUCOTROL XL	modified-release film-coated tablets	10 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	12730	2019	01
GLIPIZIDUM	GLUCOTROL XL	modified-release film-coated tablets	5 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	12729	2019	01
GRANISETRONUM HYDROCHLORIDE	GRANORED	film-coated tablets	1mg	DR. REDDY'S LABORATORIES	ROMANIA	12825	2019	01
HALOPERIDOLUM	HALOPERIDOL ROMPHARM	oral drops, solution	2mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	12618	2019	01
HOMEOPATE	FLUCIN	tablets		BIOLOGISCHE HEILMITTEL HEEL GMBH	GERMANY	12828	2019	01
HYDROCORTISONUM	HIDROCORTIZON ROMPHARM	powder for concentrate for	100mg	ROMPHARM COMPANY S.R.L.	ROMANIA	12541	2019	01

		solution for infusion/injection						
IBUPROFENUM	IBALGIN JUNIOR	oral suspension	200mg/ml	SANOFI ROMANIA SRL	ROMANIA	12590	2019	01
IBUPROFENUM	IBUPROFEN banner	chewable tablets	100mg	PATHEON B.V	HOLLAND	12778	2019	01
IBUPROFENUM	LAROFEN	film-coated tablets	200 mg	LAROPHARM S.R.L.	ROMANIA	12876	2019	01
IBUPROFENUM/ PSEUDOEFEDRINUM CLORHIDRAT	FLUFEN	film-coated tablets	200mg/30mg	LAROPHARM S.R.L.	ROMANIA	12889	2019	01
IBUPROFENUM + PARACETAMOLUM	ANALGEX	film-coated tablets	400 mg/ 325 mg	LAROPHARM S.R.L.	ROMANIA	12869	2019	01
IMATINIBUM	IMATINIB TERAPIA	film-coated tablets	100mg	RANBAXY PHARMACIE GENERIQUE	FRANCE	12747	2019	01
IMATINIBUM	IMATINIB TERAPIA	film-coated tablets	400mg	RANBAXY PHARMACIE GENERIQUE	FRANCE	12748	2019	01
INDAPAMIDUM	IDUREN SR	prolonged-release tablets	1.5 mg	VIM SPECTRUM S.R.L.	ROMANIA	12547	2019	01
INDAPAMIDUM	DIOPLEX SR	prolonged-release tablets	1.5mg	ANPHARM PRZEDSIEBIORSTWO FARMACEUTYCZNE S.A.	POLAND	12867	2019	01
IPATROPIUM BROMIDE/SALBUTAMOLUM SULPHATE	IPRATROPIU/SALBUTAMOL AMRING	nebuliser solution for inhalation	0.5/2.5mg	AMRING FARMA SRL	ROMANIA	12606	2019	01
IRBESARTANUM + HCTZ	CONVERIDE	film-coated tablets	150mg/ 12.5mg	MEDOCHEMIE LTD	CYPRUS	12529	2019	01
IRBESARTANUM + HCTZ	CONVERIDE	film-coated tablets	300mg/ 12.5mg	MEDOCHEMIE LTD	CYPRUS	12530	2019	01

IRBESARTANUM + HCTZ	CONVERIDE	film-coated tablets	300mg/25mg	MEDOCHEMIE LTD	CYPRUS	12531	2019	01
IZOCONAZOLUM NITRATE	IZOCONAZOL ROMINKO	ovules	600 mg	ROMINKO SA	ROMANIA	12635	2019	01
IZONIAZIDUM	IZONIAZIDA ARENA	tablets	300mg	ARENA GROUP S.A.	ROMANIA	12630	2019	01
IZONIAZIDUM	IZONIAZIDA ARENA	tablets	100mg	ARENA GROUP S.A.	ROMANIA	12629	2019	01
KETOPROFENUM	KETOSPRAY	cutaneous spray, solution	100 mg/ml	G.T.S. SOLUTION SRL	ROMANIA	12619	2019	01
LACTULOSUM	LACTULAK	oral solution	660 mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	12634	2019	01
LANSOPRAZOLUM	LANZUL	gastro-resistant capsules	30mg	KRKA D.D. NOVO MESTO	SLOVENIA	12761	2019	01
LENALIDOMIDUM	LENALIDOMIDA GRINDEKS	capsules	2.5mg	AS GRINDEKS	LATVIA	12698	2019	01
LENALIDOMIDUM	LENALIDOMIDA GRINDEKS	capsules	5mg	AS GRINDEKS	LATVIA	12699	2019	01
LENALIDOMIDUM	LENALIDOMIDA GRINDEKS	capsules	7.5mg	AS GRINDEKS	LATVIA	12700	2019	01
LENALIDOMIDUM	LENALIDOMIDA GRINDEKS	capsules	10mg	AS GRINDEKS	LATVIA	12701	2019	01
LENALIDOMIDUM	LENALIDOMIDA GRINDEKS	capsules	15mg	AS GRINDEKS	LATVIA	12702	2019	01
LENALIDOMIDUM	LENALIDOMIDA GRINDEKS	capsules	20mg	AS GRINDEKS	LATVIA	12703	2019	01
LENALIDOMIDUM	LENALIDOMIDA GRINDEKS	capsules	25mg	AS GRINDEKS	LATVIA	12704	2019	01
LEUPRORELINUM ACETATE	LEPTOPROL	implant syringe	5mg	SANDOZ d.d.	SLOVENIA	12774	2019	01

LEUPRORELINUM ACETATE	LUTRATE DEPOT	powder and solvent for suspension for injection	22.5mg	Angelini Pharma	AUSTRIA	12852	2019	01
LEVAMISOLUM	LEVAMISOL ARENA	tablets	50mg	ARENA GROUP S.A.	ROMANIA	12753	2019	01
LEVAMISOLUM	LEVAMISOL ARENA	tablets	150mg	ARENA GROUP S.A.	ROMANIA	12754	2019	01
LEVODROPROPIZINUM	LEVOPRONT	tablets	60mg	DOMPE FARMACEUTICI SPA	ITALY	12742	2019	01
LEVOFLOXACINUM	LEVALOX	film-coated tablets	250mg	KRKA D.D. NOVO MESTO	SLOVENIA	12565	2019	01
LEVOFLOXACINUM	LEVALOX	film-coated tablets	500mg	KRKA D.D. NOVO MESTO	SLOVENIA	12566	2019	01
LEVOFLOXACINUM	LEVALOX	solution for infusion	5mg/ml	KRKA D.D. NOVO MESTO	SLOVENIA	12567	2019	01
LEVONORGESTRELUM + ETHINYLESTRADIOL	SEASONIQUE	film-coated tablets	150/30mg+ 10mg	PHARMALEX GMBH	GERMANY	12865	2019	01
LIDOCAINUM HYDROCHLORIDE	LIDOCAIN	spray, solution	4,6 mg/dose	EGIS PHARMACEUTICALS PLC	HUNGARY	12783	2019	01
LINEZOLIDUM	LINEZOLID INFOMED	solution for infusion	2mg/ml	INFOMED FLUIDS S.R.L.	ROMANIA	12826	2019	01
LINEZOLIDUM	LINEZOLID ACCORD	solution for infusion	2mg/ml	ACCORD HEALTHCARE LIMITED	UK	12850	2019	01
LOPERAMIDUM CLORHIDRATUM	LOPEMIDOL	oral solution	1mg/5ml	BIOFARM S.A.	ROMANIA	12549	2019	01
LOPERAMIDUM CLORHIDRATUM	CLORHIDRAT DE LOPERAMID VIM SPECTRUM	capsules	2mg	VIM SPECTRUM S.R.L.	ROMANIA	12886	2019	01

LOPERAMIDUM HYDROCHLORIDE	LOPERAMID SOLACIUM	capsules	2mg	SOLACIUM PHARMA	ROMANIA	12577	2019	01
LOPERAMIDUM HYDROCHLORIDE	IMODIUM	orodispersible tablets	2 mg	JANSSEN CILAG S.p.A	ITALY	12758	2019	01
LORAZEPAMUM	ANXIAR	film-coated tablets	1mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	12633	2019	01
LORNOXICAMUM	LORNOXICAM ROMPHARM	powder and solvent for solution for injection	8mg	ROMPHARM COMPANY S.R.L.	ROMANIA	12769	2019	01
LOSARTANUM	LOSARTAN ARENA	film-coated tablets	25mg	ARENA GROUP S.A.	ROMANIA	12627	2019	01
LOSARTANUM	LOSARTAN ARENA	film-coated tablets	100mg	ARENA GROUP S.A.	ROMANIA	12628	2019	01
LOVASTATINUM	LOVASTATINA ARENA	tablets	20mg	ARENA GROUP S.A.	ROMANIA	12692	2019	01
MELOXICAMUM	MELOXICAM ZENTIVA	tablets	15mg	ZENTIVA k.s.	THE CZECH REPUBLIC	12579	2019	01
MELOXICAMUM	MELOXICAM VIM SPECTRUM	tablets	7.5mg	VIM SPECTRUM S.R.L.	ROMANIA	12646	2019	01
MELOXICAMUM	MELOXICAM VIM SPECTRUM	tablets	15 mg	VIM SPECTRUM S.R.L.	ROMANIA	12647	2019	01
MEPIVACAINUM HYDROCHLORIDE	MEPIDENTAL	solution for injection	30mg/ml	LAB INIBSA DENTAL SLU	SPAIN	12836	2019	01
METAMIZOLUM SODIUM	METAMIZOL SODIC PML	solution for injection	500 mg/ml	PHARMA MARKETING LINE SRL	ROMANIA	12649	2019	01
METAMIZOLUM SODIUM	ALGOSTOP	powder for oral solution	500mg	CHEMAX PHARMA LTD	BULGARIA	12693	2019	01
METAMIZOLUM SODIUM	ALGOSTOP	powder for oral solution	1000mg	CHEMAX PHARMA LTD	BULGARIA	12694	2019	01
METAMIZOLUM SODIUM	METAMIZOL SODIC SANOSAN	tablets	500 mg	SANOSAN S.R.L.	ROMANIA	12741	2019	01

METHOTREXATUM	METOJECT PEN 10 mg	solution for injection (pre-filled syringes)	10mg	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE	GERMANY	12663	2019	01
METHOTREXATUM	METOJECT PEN 12.5 mg	solution for injection (pre-filled syringes)	12.5mg	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE	GERMANY	12664	2019	01
METHOTREXATUM	METOJECT PEN 15 mg	solution for injection (pre-filled syringes)	15mg	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE	GERMANY	12665	2019	01
METHOTREXATUM	METOJECT PEN 17.5 mg	solution for injection (pre-filled syringes)	17.5mg	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE	GERMANY	12666	2019	01
METHOTREXATUM	METOJECT PEN 20 mg	solution for injection (pre-filled syringes)	20mg	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE	GERMANY	12667	2019	01
METHOTREXATUM	METOJECT PEN 22.5mg	solution for injection (pre-filled syringes)	22.5mg	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE	GERMANY	12668	2019	01
METHOTREXATUM	METOJECT PEN 25 mg	solution for injection (pre-filled syringes)	25mg	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE	GERMANY	12669	2019	01

METHOTREXATUM	METOJECT PEN 27.5 mg	solution for injection (pre-filled syringes)	27.5mg	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE	GERMANY	12670	2019	01
METHOTREXATUM	METOJECT PEN 30 mg	solution for injection (pre-filled syringes)	30mg	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE	GERMANY	12671	2019	01
METHOTREXATUM	METOJECT PEN 7.5 mg	solution for injection (pre-filled syringes)	7.5mg	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE	GERMANY	12662	2019	01
METILPREDNISOLONUM SODIUM SUCCINAT	SOLU MEDROL- ACT -O - VIAL	powder and solvent for solution for injection	250mg	PFIZER EUROPE MA EEIG	GERMANY	12873	2019	01
MIFEPRISTONUM	MYFEGINE	tablets	600 mg	NORDIC GROUP B.V.	HOLLAND	12599	2019	01
MINOXIDILUM	MINORGA	cutaneous solution	20mg/ml	LAB BAILLEUL SA	FRANCE	12603	2019	01
MINOXIDILUM	MINORGA	cutaneous solution	50mg/ml	LAB BAILLEUL SA	FRANCE	12604	2019	01
MOXIFLOXACINUM HYDROCHLORIDE	MOFLAXA	solution for infusion	400mg/250 ml	KRKA D.D. NOVO MESTO	SLOVENIA	12744	2019	01
MOXIFLOXACINUM HYDROCHLORIDE	MOFLAXA	film-coated tablets	400mg	KRKA D.D. NOVO MESTO	SLOVENIA	12743	2019	01
N-ACETYL-ASPARTYL-GLUTAMIC ADID	NAABAK	eye drops	49 mg/ml	LABORATOIRES THEA	FRANCE	12887	2019	01
NAPROXENUM	ETRIXENAL	tablets	250 mg	PROENZI s.r.o	THE CZECH REPUBLIC	12773	2019	01
NICERGOLINUM	NICERGOLINA ATB	film-coated tablets	30 mg	ANTIBIOTICE S.A.	ROMANIA	12829	2019	01

NICOTINUM	NICORETTE FRESHFRUIT	medical chewing gum	2mg	MCNEIL AB	SWEDEN	12834	2019	01
NICOTINUM	NICORETTE FRESHFRUIT	medical chewing gum	4mg	MCNEIL AB	SWEDEN	12835	2019	01
NIFURATELUM/ NISTATINUM	MACMIROR COMPLEX	soft vaginal capsules	500mg/ 200000 IU	POLICHEM SA	LUXEMBOURG	12576	2019	01
OLMESARTAN MEDOXOMIL	OLMETEC	film-coated tablets	10mg	ALVOGEN IPCO S.A.R.L.	MALTA	12684	2019	01
OLMESARTAN MEDOXOMIL	OLMETEC	film-coated tablets	20mg	ALVOGEN IPCO S.A.R.L.	MALTA	12685	2019	01
OLMESARTAN MEDOXOMIL	OLMETEC	film-coated tablets	40mg	ALVOGEN IPCO S.A.R.L.	MALTA	12686	2019	01
OMEPRAZOLUM	OMEZ	gastro-resistant capsules	10mg	DR. REDDY'S LABORATORIES	ROMANIA	12714	2019	01
OMEPRAZOLUM	OMEZ	gastro-resistant capsules	20mg	DR. REDDY'S LABORATORIES	ROMANIA	12715	2019	01
OMEPRAZOLUM	OMEZ	gastro-resistant capsules	40mg	DR. REDDY'S LABORATORIES	ROMANIA	12716	2019	01
PANTOPRAZOLUM	PANTOPRAZOL TORRENT	gastro-resistant tablets	20mg	TORRENT PHARMA SRL	ROMANIA	12808	2019	01
PANTOPRAZOLUM	PANTOPRAZOL TORRENT	gastro-resistant tablets	40mg	TORRENT PHARMA SRL	ROMANIA	12809	2019	01
PANTOPRAZOLUM SODIUM	NOLPANTA	gastro-resistant tablets	20 mg	KRKA D.D. NOVO MESTO	SLOVENIA	12675	2019	01
PARACETAMOLUM	DALERON	oral suspension	120 mg/5 ml	KRKA D.D. NOVO MESTO	SLOVENIA	12639	2019	01

PARACETAMOLUM	PARACETAMOL PHARMA MARKETING LINE	tablets	500 mg	PHARMA MARKETING LINE SRL	ROMANIA	12696	2019	01
PARACETAMOLUM	DALERON	tablets	500mg	KRKA D.D. NOVO MESTO	SLOVENIA	12807	2019	01
PARACETAMOLUM	PANADOL RAPID	film-coated tablets	500mg	GLAXOSMITHKLINE CONSUMER HEALTHCARE	ROMANIA	12831	2019	01
PARACETAMOLUM	PARACETAMOL ZENTIVA	tablets	500mg	ZENTIVA S.A.	ROMANIA	12881	2019	01
PARACETAMOLUM	PARACETAMOL SOLACIUM	tablets	500mg	SOLACIUM PHARMA	ROMANIA	12882	2019	01
PARACETAMOLUM + PHENYLEPHRINE HCL	ANTINEVRALGIC SINUS HOT DRINK	powder for oral suspension	650 mg/10 mg	ZENTIVA k.s.	THE CZECH REPUBLIC	12752	2019	01
PARACETAMOLUM + PSEUDOEPHEDRINE HYDROCHLORIDE	FLUSIN	film-coated tablets	500mg/30 mg	LAROPHARM S.R.L.	ROMANIA	12888	2019	01
PERINDOPRILUM ARGININE	PRESTORVAL	film-coated tablets	5mg	ANPHARM PRZEDSIEBIORSTWO FARMACEUTYCZNE S.A.	POLAND	12780	2019	01
PERINDOPRILUM ARGININE	PRESTORVAL	film-coated tablets	10mg	ANPHARM PRZEDSIEBIORSTWO FARMACEUTYCZNE S.A.	POLAND	12781	2019	01
PERINDOPRILUM ARGININE + INDAPAMIDUM	NORIPLEX	film-coated tablets	2.5mg/ 0.625 mg	ANPHARM PRZEDSIEBIORSTWO FARMACEUTYCZNE S.A.	POLAND	12779	2019	01
PERINDOPRILUM TERT-BUTYLAMINE	ERNYOM	tablets	4mg	VIM SPECTRUM S.R.L.	ROMANIA	12631	2019	01

PERINDOPRILUM TERT-BUTYLAMINE	ERNYOM	tablets	8mg	VIM SPECTRUM S.R.L.	ROMANIA	12632	2019	01
PHENYLEPHRINUM HYDROCHLORIDE	FENILEFRINA HYPERICUM	solution for injection (pre-filled syringes)	50mcg/ml	HYPERICUM	ROMANIA	12622	2019	01
PHENYLEPHRINUM HYDROCHLORIDE	BIORPHEN	solution for injection/infusion	0.1mg/ml	SINTETICA GMBH	GERMANY	12821	2019	01
PHENYLEPHRINUM HYDROCHLORIDE	BIORPHEN	solution for injection	10mg/ml	SINTETICA GMBH	GERMANY	12822	2019	01
PIOGLITAZONE HYDROCHLORIDE	PIOGLITAZONA TORRENT	film-coated tablets	15mg	TORRENT PHARMA GMBH	GERMANY	12736	2019	01
PIRACETAMUM	PRAMISTAR	film-coated tablets	600mg	F.I.R.M.A. S.p.A	ITALY	12841	2019	01
PIRACETAMUM	PIRACETAM HELCOR	film-coated tablets	400mg	AC HELCOR PHARMA SRL	ROMANIA	12871	2019	01
PIRACETAMUM	PIRACETAM HELCOR	film-coated tablets	800mg	AC HELCOR PHARMA SRL	ROMANIA	12872	2019	01
HERBS	SINUPRET ACUTE	coated tablets		BIONORICA SE	GERMANY	12539	2019	01
HERBS	GRANU FINK PROSTA	capsules		PROMAROM S.R.L	ROMANIA	12588	2019	01
HERBS	BRONCHOSTOP DUO	tablets		KWIZDA PHARMA GmnH	AUSTRIA	12613	2019	01
HERBS	GRANU FINK Uro	capsules		PROMAROM S.R.L	ROMANIA	12648	2019	01
HERBS	GRANU FINK PROSTA FORTE	capsules		PROMAROM S.R.L	ROMANIA	12695	2019	01
HERBS	CANEPHRON	oral drops, solution		BIONORICA SE	GERMANY	12724	2019	01
HERBS	TAVIPEC	gastro-resistant tablets	150 mg	PHARMAZEUTISCHE FABRIK MONTAVIT Ges.m.B.H	AUSTRIA	12788	2019	01

HERBS	CANEPHRON	coated tablets		BIONORICA SE	GERMANY	12762	2019	01
HERBS	PROSPAN	oral solution	35 mg/5 ml	ENGELHARD ARZNEIMITTEL GmbH&Co.KG	GERMANY	12868	2019	01
POSACONAZOLUM	POSACONAZOL ZENTIVA	gastro-resistant tablets	100mg	DELORBIS PHARMACEUTICALS Ltd	CYPRUS	12621	2019	01
POSACONAZOLUM	POSACONAZOL MYLAN	gastro-resistant tablets	100mg	MYLAN S.A.S.	FRANCE	12723	2019	01
POSACONAZOLUM	POSACONAZOL ALVOGEN	gastro-resistant tablets	100 mg	ALVOGEN IPCO S.A.R.L.	MALTA	12737	2019	01
PREDNISOLONUM	PREDNISON RICHTER	tablets	5 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	12885	2019	01
PREGABALINUM	PREGABALIN TERAPIA	capsules	75mg	TERAPIA S.A	ROMANIA	12858	2019	01
PREGABALINUM	PREGABALIN TERAPIA	capsules	125mg	TERAPIA S.A.	ROMANIA	12861	2019	01
PREGABALINUM	PREGABALIN TERAPIA	capsules	150mg	TERAPIA S.A	ROMANIA	12859	2019	01
PREGABALINUM	PREGABALIN TERAPIA	capsules	175mg	TERAPIA S.A	ROMANIA	12862	2019	01
PREGABALINUM	PREGABALIN TERAPIA	capsules	300mg	TERAPIA S.A	ROMANIA	12860	2019	01
PREGABALINUM	PREGABALIN TERAPIA	capsules	250mg	TERAPIA S.A	ROMANIA	12863	2019	01
PREGABALINUM	PREGABALIN TERAPIA	capsules	275mg	TERAPIA S.A.	ROMANIA	12864	2019	01
BIOLOGICAL PRODUCTS	VARIVAX	powder and solvent for solution for injection		MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	12595	2019	01
RADIOPHARMACEUTICALS	FLUDEOXIGLUCOZA (18 F) MONROL	solution for injection	200-2200 mbq/ml	MONROL EUROPE S.R.L.	ROMANIA	12600	2019	01
RANITIDINUM	RANITIDINA LAROPHARM	film-coated tablets	150 mg	LAROPHARM S.R.L.	ROMANIA	12572	2019	01

RANITIDINUM HYDROCHLORIDE	RANITIDINA	tablets	150mg	MAGISTRA C&C SRL	ROMANIA	12548	2019	01
RANITIDINUM HYDROCHLORIDE	RANITIDIN HELCOR	film-coated tablets	150 mg	AC HELCOR SRL	ROMANIA	12782	2019	01
RANITIDINUM HYDROCHLORIDE	RANITIDINA HELCOR	film-coated tablets	75 mg	AC HELCOR SRL	ROMANIA	12830	2019	01
RIBAVIRINUM	RIBAVIRINA AUROBINDO	film-coated tablets	200mg	AUROBINDO PHARMA LIMITED	MALTA	12558	2019	01
RISPERIDONUM	TORENDO Q TAB	orodispersible tablets	3mg	KRKA D.D. NOVO MESTO	SLOVENIA	12688	2019	01
RISPERIDONUM	TORENDO Q TAB	orodispersible tablets	4mg	KRKA D.D. NOVO MESTO	SLOVENIA	12689	2019	01
RIVASTIGMINUM	RIVASTIGMINA STADA	transdermal patch	4.6mg/24 h	STADA HEMOFARM S.R.L.	ROMANIA	12800	2019	01
RIVASTIGMINUM	RIVASTIGMINA STADA	transdermal patch	9.5mg/24 h	STADA HEMOFARM S.R.L.	ROMANIA	12801	2019	01
ROPINIROLUM HYDROCHLORIDE	ROPINIROL ARENA	film-coated tablets	0.25mg	ARENA GROUP S.A.	ROMANIA	12542	2019	01
ROPINIROLUM HYDROCHLORIDE	ROPINIROL ARENA	film-coated tablets	0.5mg	ARENA GROUP S.A.	ROMANIA	12543	2019	01
ROPINIROLUM HYDROCHLORIDE	ROPINIROL ARENA	film-coated tablets	1mg	ARENA GROUP S.A.	ROMANIA	12544	2019	01
ROPINIROLUM HYDROCHLORIDE	ROPINIROL ARENA	film-coated tablets	5mg	ARENA GROUP S.A.	ROMANIA	12546	2019	01
ROPINIROLUM HYDROCHLORIDE	ROPINIROL ARENA	film-coated tablets	2mg	ARENA GROUP S.A.	ROMANIA	12545	2019	01
ROSUVASTATINUM CALCIUM	ROSUVASTATIN ATB	film-coated tablets	5mg	ANTIBIOTICE S.A.	ROMANIA	12534	2019	01
ROSUVASTATINUM CALCIUM	ROSUVASTATIN ATB	film-coated tablets	10mg	ANTIBIOTICE S.A.	ROMANIA	12535	2019	01

ROSUVASTATINUM CALCIUM	ROSUVASTATIN ATB	film-coated tablets	20mg	ANTIBIOTICE S.A.	ROMANIA	12536	2019	01
ROSUVASTATINUM CALCIUM	ROSUVASTATIN ATB	film-coated tablets	40mg	ANTIBIOTICE S.A.	ROMANIA	12537	2019	01
ROSUVASTATINUM CALCIUM	ROSUVASTATINA MSN LABORATORIES	film-coated tablets	5mg	VIVANTA GENERICS sro	THE CZECH REPUBLIC	12705	2019	01
ROSUVASTATINUM CALCIUM	ROSUVASTATINA MSN LABORATORIES	film-coated tablets	10mg	VIVANTA GENERICS sro	THE CZECH REPUBLIC	12706	2019	01
ROSUVASTATINUM CALCIUM	ROSUVASTATINA MSN LABORATORIES	film-coated tablets	20mg	VIVANTA GENERICS sro	THE CZECH REPUBLIC	12707	2019	01
ROSUVASTATINUM CALCIUM	ROSUVASTATINA MSN LABORATORIES	film-coated tablets	40mg	VIVANTA GENERICS sro	THE CZECH REPUBLIC	12708	2019	01
SEVELAMERUM HYDROCHORIDE	CLORHIDRAT DE SEVELAMER	film-coated tablets	400mg	WAYMADE B.V.	HOLLAND	12624	2019	01
SEVELAMERUM HYDROCHORIDE	CLORHIDRAT DE SEVELAMER	film-coated tablets	800mg	WAYMADE B.V.	HOLLAND	12625	2019	01
SPIRONOLACTONUM	SPIRONOLACTONA LPH	capsules	25mg	LABORMED PHARMA S.A.	ROMANIA	12614	2019	01
SPIRONOLACTONUM/ FUROSEMIDUM	DIUROCARD 50 mg/20 mg	capsules	50 mg/20 mg	LABORMED PHARMA S.A.	ROMANIA	12842	2019	01
SULODEXIDUM	COREFLUX	soft capsules	250 uls	SANIENCE SRL	ROMANIA	12805	2019	01
SULODEXIDUM	COREFLUX	solution for injection	600 uls/2 ml	SANIENCE SRL	ROMANIA	12806	2019	01
TACROLIMUS MONOHIDRATE	DAILIPORT	capsules	0.5mg	SANDOZ S.R.L.	AUSTRIA	12731	2019	01
TACROLIMUS MONOHIDRATE	DAILIPORT	capsules	1mg	SANDOZ S.R.L.	AUSTRIA	12732	2019	01
TACROLIMUS MONOHIDRATE	DAILIPORT	capsules	3mg	SANDOZ S.R.L.	AUSTRIA	12734	2019	01
TACROLIMUS MONOHIDRATE	DAILIPORT	capsules	5mg	SANDOZ S.R.L.	AUSTRIA	12735	2019	01
TACROLIMUS MONOHIDRATE	DAILIPORT	capsules	2mg	SANDOZ S.R.L.	AUSTRIA	12733	2019	01
TAMOXIFENUM CITRATE	TAMOXIFEN CREATIVE PHARMA SOLUTIONS	tablets	10mg	CREATIVE PHARMA	THE CZECH REPUBLIC	12745	2019	01

TAMOXIFENUM CITRATE	TAMOXIFEN CREATIVE PHARMA SOLUTIONS	tablets	20mg	CREATIVE PHARMA	THE CZECH REPUBLIC	12746	2019	01
TAMSULOSIN HYDROCHLORIDE	TAMSOL	modified-release capsules	0.4mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	12674	2019	01
TERLIPRESSINUM	GLYPRESSIN	solution for injection	0.1 mg/ml	FERRING GmbH	GERMANY	12586	2019	01
TIGECICLINUM	TIGECICLINA FRESENIUS KABI	powder for solution for injection/infusion	50mg	FRESENIUS KABI AUSTRIA GMBH	AUSTRIA	12589	2019	01
TRANDOLAPRILUM	TRANDOLAPRIL ARENA	capsules	0.5mg	ARENA GROUP	ROMANIA	12568	2019	01
TRANDOLAPRILUM	TRANDOLAPRIL ARENA	capsules	1mg	ARENA GROUP	ROMANIA	12569	2019	01
TRANDOLAPRILUM	TRANDOLAPRIL ARENA	capsules	2mg	ARENA GROUP	ROMANIA	12570	2019	01
TRANDOLAPRILUM	TRANDOLAPRIL ARENA	capsules	4mg	ARENA GROUP	ROMANIA	12571	2019	01
TREPROSTINILUM	TRESUVI	solution for infusion	1.0mg/ml	AMOMED PHARMA GmbH	AUSTRIA	12561	2019	01
TREPROSTINILUM	TRESUVI	solution for infusion	2.5mg/ml	AMOMED PHARMA GmbH	AUSTRIA	12562	2019	01
TREPROSTINILUM	TRESUVI	solution for infusion	50.mg/ml	AMOMED PHARMA GmbH	AUSTRIA	12563	2019	01
TREPROSTINILUM	TRESUVI	solution for infusion	10.0mg/ml	AMOMED PHARMA GmbH	AUSTRIA	12564	2019	01
TRIMEBUTINUM	DEBRIDAT	granules for oral suspension	24mg/5ml	PFIZER EUROPE MA EEIG	GREAT BRITAIN	12584	2019	01
TRIMEBUTINUM MALEATE	DEBRIDAT	film-coated tablets	100mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	12582	2019	01
TRIMEBUTINUM MALEATE	DEBRIDAT	film-coated tablets	200mg	PFIZER EUROPE MA EEIG	UK	12583	2019	01
VERAPAMILUM HYDROCHLORIDE/ TRANDOLAPRIL	TARKA	modified release tablets	240mg/2mg	MYLAN HEALTHCARE GmbH	GERMANY	12644	2019	01

VERAPAMILUM HYDROCHLORIDE/ TRANDOLAPRIL	TARKA	modified release tablets	240mg/4mg	MYLAN HEALTHCARE GmbH	GERMANY	12645	2019	01
VINORELBINUM TARTRATE	NAVELBINE	capsules	20 mg	PIERRE FABRE MEDICAMENT	FRANCE	12681	2019	01
VINORELBINUM TARTRATE	NAVELBINE	capsules	30 mg	PIERRE FABRE MEDICAMENT	FRANCE	12682	2019	01

Centrally authorised medicinal products notified for marketing in Romania during the 4th quarter of 2019

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
ARSENICUM TRIOXIDUM	ARSENIC TRIOXIDE ACCORD 1 mg/ml	concentrate for solution for infusion	1 mg/ml	ACCORD HEALTHCARE S.L.U.	SPAIN	1398	18.11.2019	03
BORTEZOMIBUM	BORTEZOMIB FRESENIUS KABI 3.5 mg	powder for solution for injection	3.5mg	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	1397	18.11.2019	01
ESKETAMINUM	SPRAVATO 28 mg	nasal spray, solution	28mg	JANSSEN CILAG INTERNATIONAL NV	BELGIA	1410	18.12.2019	03
GLUCAGONUM	BAQSIMI 3 mg	single dose nasal powder	3mg	ELI LILLY NEDERLAND B.V.	HOLLAND	1406	18.12.2019	02
METFORMINUM + SAXAGLIPTINUM + DAPAGLIFOZINUM	QTRILMET 1000 mg/2.5 mg/ 5 mg	modified release tablets	1000mg/ 2.5mg/5mg	ASTRA ZENECA AB	SWEDEN	1401	11.11.2019	27
TOFACITINIB	XELJANZ 11 mg	prolonged release tablets	11mg	PFIZER EUROPE MA EEIG	BELGIA	1178	16.12.2019	13
UPADACITINIBUM	RINVOQ 15 mg	prolonged release tablets	15mg	ABBVIE DEUTSCHLAND GMBH & CO. KG	GERMANY	1404	18.12.2019	01