

ROMANIA

Newsletter

Year 24, No. 2 (94), 2nd quarter of 2022

*National Agency
for Medicines and Medical Devices
of Romania*

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The Newsletter of the National Agency for Medicines and Medical Devices of Romania contains the following:

- information of public interest communicated ex officio, provided in Article 5 paragraph 2 of Law no. 544/2001:

a) The ruling provisions regulating the organisation and operation of the NAMMDR are the following:

Law no. 134 of 12 July 2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions;;

Order no. 1412 of 13 September 2019 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania;

Order no. 1.522 of 9 October 2019 on approval of the Regulation for organisation and operation of the National Agency for Medicines and Medical Devices of Romania.

b) The public institution's organisation chart, attributions of each department, working programme, audience programme:

Regulation for organisation and operation of the National Agency for Medicines and Medical Devices of Romania

c) Names and surnames of the persons of the public institution's management, responsible for the dissemination of public information

d) The institution's contact data

e) Audiences

Business hours

f) Financial sources, budget and the balance sheet

Budget and funding source

Balance sheet

g) The institution's programmes and strategies

h) Public documents and NAMMDR managed/generated documents

**i) Challenge of decisions and associated forms for administrative complaint
(refusal and failure to comply with legal deadlines)**

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Laws

Title XX of Law 95/2006, version published in the Official Gazette of Romania no. 391/21.04.2022

Orders of the Minister of Health

Order of the Minister of Health no. 1.171/2022 on approval of the procedure for issuance of a free sale certificate for medical devices

Order of the Minister of Health no. 85/2013 of 7 February 2013 on approval of the Norms for implementation of provisions of Article 699 (1) and (2) of Law No. 95/2006 on healthcare reform concerning medicinal products for special needs, **version updated in May 2022.**

Medicinal product batches recalled during the 2nd quarter of 2022

| No. | Product recalled | Pharmaceutical form | Strength | INN | Manufacturer/MAH | Batch | Grounds for recall | Proposed action | Date of recall |
|-----|-----------------------------------|-----------------------|-----------|--------------------------------------|----------------------------------|--|---|--|----------------|
| 1 | Vitafusal solution for infusion | solution for infusion | | combination | Infomed Fluid, Romania | | European Commission Decision no. C(2022)3591-final of 24.06.2022: suspension of MAs for medicinal products containing hydroxyethyl starch (HES), solutions for infusion | Recall from the market at pharmacy level and destruction | 28.07.2022 |
| 2 | Accupro 5 mg film-coated tablets | film-coated tablets | 5 mg | quinapril as quinapril hydrochloride | PFIZER EUROPE MA EEIG, Belgium | DA9323 CM3656 CY4275 CY4268 CY4274 FP8298 | Nitrosamine impurity: N-nitroso-quinapril, and test results have shown, in certain batches of the finished product, a content of N-nitroso-quinapril that exceeds the acceptable daily intake | Recall and destruction | 14.05.2022 |
| 3 | Accupro 10 mg film-coated tablets | film-coated tablets | 10 mg | quinapril as quinapril hydrochloride | PFIZER EUROPE MA EEIG, Belgium | DM6649 DW3855 FE6829 FG9061 FJ0425 | Nitrosamine impurity: N-nitroso-quinapril, and test results have shown, in certain batches of the finished product, a content of N-nitroso-quinapril that exceeds the acceptable daily intake | Recall and destruction | 14.05.2022 |
| 4 | Accupro 20 mg film-coated tablets | film-coated tablets | 20 mg | quinapril as quinapril hydrochloride | PFIZER EUROPE MA EEIG, Belgium | DA9322 DG7393 FD9330 FK8586 FN7571 | Nitrosamine impurity: N-nitroso-quinapril, and test results have shown, in certain batches of the finished product, a content of N-nitroso-quinapril that exceeds the acceptable daily intake | Recall and destruction | 14.05.2022 |
| 5 | Vigantol OIL | oral drops, solution | 0.5 mg/ml | cholecalciferol | P&G Health Germany GmbH, Germany | 19KQ042 20CQ046 | voluntary recall at warehouse and pharmacy level, following an out-of-specification (OOS) result for the „cholecalciferol content" parameter | Voluntary recall and destruction | 09.05.2022 |

Applications for marketing authorisation/marketing authorisation renewal received during the 1st quarter of 2022

In the 1st quarter of 2022, 10 marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

| |
|---|
| J01 - ANTIBACTERIALS FOR SYSTEMIC USE |
| B01A – ANTITHROMBOTIC AGENTS |
| J01 - ANTIBACTERIALS FOR SYSTEMIC USE |
| J01 - ANTIBACTERIALS FOR SYSTEMIC USE |
| C08 – CALCIUM CHANNEL BLOCKERS |
| V03 - ALL OTHER THERAPEUTIC PRODUCTS |
| A10 – DRUGS USED IN DIABETES |
| A10 – DRUGS USED IN DIABETES |
| V08 – CONTRAST MEDIA |
| J01D – OTHER BETA-LACTAM ANTIBACTERIALS |

Medicinal products authorised for marketing during the 1st quarter of 2022

| INN | Trade name | Pharmaceutical form | Strength | MAH | Holding country | MA no. | |
|--------------------------|----------------------------------|--|----------|--|-----------------|-----------|------|
| ACIDUM ASCORBICUM | VITAMINA C ZENTIVA 100 mg/ml | solution for injection/infusion | 100mg/ml | ZENTIVA S.A. | ROMANIA | 1437 0 | 2022 |
| ACIDUM URSODEOXYCHOLICUM | URSOGRIX 250 mg | capsules | 250mg | AS GRINDEKS | LETONIA | 1434 9 | 2022 |
| ALBUMINUM HUMANUM | ALBUTEIN 50 g/l | solution for infusion | 50g/l | INSTITUTO GRIFOLS, S.A. | SPAIN | 1431 4 | 2022 |
| ALBUMINUM HUMANUM | ALBUTEIN 200 g/l | solution for infusion | 200g/l | INSTITUTO GRIFOLS, S.A. | SPAIN | 1431 5 | 2022 |
| AZACITIDINUM | AZACITIDINA ONKO 25 mg/ml | powder for suspension for injection | 25mg/ml | ONKO PHARMACEUTICALS BULGARIA LTD EOOD | BULGARIA | 1428 4 | 2022 |
| AZITHROMYCINUM | AZIBIOT 20 mg/ml | powder for oral suspension | 20mg/ml | KRKA, D.D., NOVO MESTO | SLOVENIA | 1432 2 | 2022 |
| AZITHROMYCINUM | AZIBIOT 40 mg/ml | powder for oral suspension | 40mg/ml | KRKA, D.D., NOVO MESTO | SLOVENIA | 1432 3 | 2022 |
| BENDAMUSTINUM | BENDAMUSTINA ACCORD 2.5 mg/ml | powder for concentrate for solution for infusion | 2.5mg/ml | ACCORD HEALTHCARE POLSKA SP. Z O.O. | POLAND | 1433 2 | 2022 |
| BETAHISTINUM | BETAHISTINA ATB 8 mg | tablets | 8mg | ANTIBIOTICE S.A. | ROMANIA | 1432 7 | 2022 |
| BETAHISTINUM | BETAHISTINA ATB 24 mg | tablets | 24mg | ANTIBIOTICE S.A. | ROMANIA | 1432 8 | 2022 |

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|---------------|--|--|--------|---|----------|-----------|------|
| BUPIVACAINUM | BUPIVACAINA SPINAL HEAVY PANPHARMA 5 mg/ml | solution for injection | 5mg/ml | PANPHARMA | FRANCE | 1432 5 | 2022 |
| BUPIVACAINUM | BUPIVACAINA ROMPHARM 5 mg/ml | solution for injection | 5mg/ml | ROMPHARM COMPANY S.R.L. | ROMANIA | 1432 6 | 2022 |
| CABAZITAXELUM | CABAZITAXEL MSN 60 mg | concentrate and solvent for solution for infusion | 60mg | MSN LABS EUROPE LIMITED | MALTA | 1431 1 | 2022 |
| CARMUSTINUM | CARMUSTINA WAYMADE 100 mg | powder and solvent for concentrate for solution for infusion | 100mg | WAYMADE B.V. | HOLLAND | 1432 1 | 2022 |
| CEFTAZIDIMUM | CEFTAZIDIMA APTAPHARMA 2 g | powder for solution for injection/infusion | 2g | APTA MEDICA INTERNACIONAL D.O.O | SLOVENIA | 1429 4 | 2022 |
| CINACALCETUM | CINACALCET ACCORD 30 mg | film-coated tablets | 30mg | ACCORD HEALTHCARE POLSKA SP. Z O.O. | POLAND | 1426 8 | 2022 |
| CLINDAMYCINUM | OVYX 100 mg | ovules | 100mg | MAGNAPHARM MARKETING & SALES ROMANIA S.R.L. | ROMANIA | 1424 3 | 2022 |
| CLOTRIMAZOLUM | CANESTEN GYN UNO 500 mg | soft vaginal capsules | 500 mg | BAYER S.R.L. | ROMANIA | 1426 6 | 2022 |
| COLCHICINUM | COLCHICINA PHARMASELECT 1 mg | tablets | 1mg | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | AUSTRIA | 1426 3 | 2022 |

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|--------------|--|--|-----------------------------|---|---------|-----------|------|
| COLCHICINUM | COLCHICINA PHARMASELECT 0.5 mg | tablets | 0.5mg | PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH | AUSTRIA | 1426 2 | 2022 |
| COMBINATIONS | SOLUTIE RINGER LACTAT B. BRAUN | solution for infusion | | B. BRAUN MELSUNGEN AG | GERMANY | 1437 8 | 2022 |
| COMBINATIONS | SOLUTIE RINGER B. BRAUN | solution for infusion | | B. BRAUN MELSUNGEN AG | GERMANY | 1437 7 | 2022 |
| COMBINATIONS | SOLUTIE RINGER B. BRAUN PLASCO | solution for infusion | | B. BRAUN MELSUNGEN AG | GERMANY | 1437 9 | 2022 |
| COMBINATIONS | REVIGRIP HOT LEMON 500 mg/200 mg/10 mg | powder for oral solution | 500mg/ 200mg/10mg | CHEFARO IRELAND DAC | IRELAND | 1426 5 | 2022 |
| COMBINATIONS | COLDREX SINUMAX RACEALA SI TUSE 1000 mg/200 mg/12.2 mg | powder for oral solution | 1000mg/ 200mg/ 12.2mg | PERRIGO ROMANIA S.R.L. | ROMANIA | 1431 0 | 2022 |
| COMBINATIONS | THERAFLU RACEALA SI TUSE 500 mg/6.1 mg/100 mg | capsules | 500mg/6.1mg /100mg | GLAXOSMITHKLINE CONSUMER HEALTHCARE SRL | ROMANIA | 1427 2 | 2022 |
| COMBINATIONS | THERAFLU MAX RACEALA SI TUSE 1000 mg/12.2 mg/200 mg | powder for oral solution | 1000mg/ 12.2mg/ 200mg | GLAXOSMITHKLINE CONSUMER HEALTHCARE SRL | ROMANIA | 1427 1 | 2022 |
| COMBINATIONS | CLENSIA | powder for oral suspension | | ADDENDA PHARMACEUTICAL S S.R.L. | ROMANIA | 1433 5 | 2022 |
| COMBINATIONS | GLUCOTHERA 1.4 m/v GLUCOZA | solution for peritoneal dialysis | | IPERBOREAL PHARMA S.R.L. | ITALY | 1427 9 | 2022 |
| COMBINATIONS | GLUCOTHERA 2.4 m/v GLUCOZA | solution for peritoneal dialysis | | IPERBOREAL PHARMA S.R.L. | ITALY | 1428 0 | 2022 |

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|--|--|--|--------------------------|---|-----------------------|-----------|------|
| COMBINATIONS | GLUCOTHERA 4 m/v GLUCOZA | solution for peritoneal dialysis | | IPERBOREAL PHARMA S.R.L. | ITALY | 1428 1 | 2022 |
| COMBINATIONS | SEPTOFAR MENTA 0.6 mg/1.2 mg | pills | 0.6mg/1.2mg | DR. MAX PHARMA S.R.O. | THE CZECH REPUBLIC | 1426 7 | 2022 |
| COMBINATIONS | NEUROMULTIVIT 110 mg/100 mg/1 mg/2 ml | solution for injection | 110mg/100mg /1mg/2ml | LANNACHER HEILMITTEL GES.M.B.H. | AUSTRIA | 1433 3 | 2022 |
| COMBINATIONS | SMOFKABIVEN NUTRIBASE | emulsion for infusion | | FRESENIUS KABI ROMANIA SRL | ROMANIA | 1435 3 | 2022 |
| COMBINATIONS (ACICLOVIRUM+ HYDROCORTISONUM) | ZOVIRAX DUO 50 mg/10 mg/g | cream | 50mg/10mg/g | GLAXOSMITHKLINE CONSUMER HEALTHCARE S.R.L. | ROMANIA | 1434 4 | 2022 |
| COMBINATIONS (ADAPALENUM+ BENZOYLIS PEROXIDUM) | EPIDUO 1 mg/25 mg/g | gel | 1mg/25mg/g | GALDERMA INTERNATIONAL | FRANCE | 1434 3 | 2022 |
| COMBINATIONS (CALCIPOTRIOLUM+ BETAMETHASONUM) | ENSTILUM 50 micrograms/0.5 mg/g | cutaneous foam | 50micrograms /0.5mg/g | LEO PHARMA A/S | DENMARK | 1425 8 | 2022 |
| COMBINATIONS (CARVEDILOLUM+ IVABRADINUM) | CARIVALAN 6.25 mg/5 mg | film-coated tablets | 6.25mg/5mg | LES LABORATOIRES SERVIER | FRANCE | 1435 5 | 2022 |
| COMBINATIONS (CARVEDILOLUM+ IVABRADINUM) | CARIVALAN 6.25 mg/7.5 mg | film-coated tablets | 6.25mg/7.5mg | LES LABORATOIRES SERVIER | FRANCE | 1435 6 | 2022 |
| COMBINATIONS (CARVEDILOLUM+ IVABRADINUM) | CARIVALAN 12.5 mg/5 mg | film-coated tablets | 12.5mg/5mg | LES LABORATOIRES SERVIER | FRANCE | 1435 7 | 2022 |

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|--|--|------------------------|------------------|--------------------------------------|-----------------------|-----------|------|
| COMBINATIONS (CARVEDILOLUM+ IVABRADINUM) | CARIVALAN 12.5 mg/7.5 mg | film-coated tablets | 12.5mg/7.5mg | LES LABORATOIRES SERVIER | FRANCE | 1435 8 | 2022 |
| COMBINATIONS (CARVEDILOLUM+ IVABRADINUM) | CARIVALAN 25 mg/5 mg | film-coated tablets | 25mg/5mg | LES LABORATOIRES SERVIER | FRANCE | 1435 9 | 2022 |
| COMBINATIONS (CARVEDILOLUM+ IVABRADINUM) | CARIVALAN 25 mg/7.5 mg | film-coated tablets | 25mg/7.5mg | LES LABORATOIRES SERVIER | FRANCE | 1436 0 | 2022 |
| COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM) | COLEATEZ 10 mg/10 mg | film-coated tablets | 10mg/10mg | SANDOZ S.R.L. | ROMANIA | 1433 6 | 2022 |
| COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM) | COLEATEZ 10 mg/20 mg | film-coated tablets | 10mg/20mg | SANDOZ S.R.L. | ROMANIA | 1433 7 | 2022 |
| COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM) | COLEATEZ 10 mg/40 mg | film-coated tablets | 10mg/40mg | SANDOZ S.R.L. | ROMANIA | 1433 8 | 2022 |
| COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM) | COLEATEZ 10 mg/80 mg | film-coated tablets | 10mg/80mg | SANDOZ S.R.L. | ROMANIA | 1433 9 | 2022 |
| COMBINATIONS (IBUPROFENUM+CODEINUM) | IBUVALEN DUO 200 mg/12.8 mg | film-coated tablets | 200mg/ 12.8mg | POLISANO PHARMACEUTICA LS S.A. | ROMANIA | 1437 2 | 2022 |
| COMBINATIONS (METRONIDAZOLUM+ CLOTRIMAZOLUM) | MECLODIN | vaginal tablets | 500mg/200mg | ARENA GROUP S.A. | ROMANIA | 1431 9 | 2022 |
| COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM) | PERINDOPRIL/ AMLODIPINA ZENTIVA 4 mg/5 mg | tablets | 4mg/5mg | ZENTIVA K.S. | THE CZECH REPUBLIC | 1427 4 | 2022 |

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| COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM) | PERINDOPRIL/ AMLODIPINA ZENTIVA 4 mg/10 mg | tablets | 4mg/10mg | ZENTIVA K.S. | THE CZECH REPUBLIC | 1427 5 | 2022 |
| COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM) | PERINDOPRIL/ AMLODIPINA ZENTIVA 8 mg/5 mg | tablets | 8mg/5mg | ZENTIVA K.S. | THE CZECH REPUBLIC | 1427 6 | 2022 |
| COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM) | PERINDOPRIL/ AMLODIPINA ZENTIVA 8 mg/10 mg | tablets | 8mg/10mg | ZENTIVA K.S. | THE CZECH REPUBLIC | 1427 7 | 2022 |
| COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM) | AMLESSANEO 5 mg/5 mg | tablets | 5mg/5mg | KRKA, D.D., NOVO MESTO | SLOVENIA | 1434 5 | 2022 |
| COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM) | AMLESSANEO 5 mg/10 mg | tablets | 5mg/10mg | KRKA, D.D., NOVO MESTO | SLOVENIA | 1434 6 | 2022 |
| COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM) | AMLESSANEO 10 mg/5 mg | tablets | 10mg/5mg | KRKA, D.D., NOVO MESTO | SLOVENIA | 1434 7 | 2022 |
| COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM) | AMLESSANEO 10 mg/10 mg | tablets | 10mg/10mg | KRKA, D.D., NOVO MESTO | SLOVENIA | 1434 8 | 2022 |
| COMBINATIONS (SITAGLIPTINUM+ METFORMINUM) | JUZIMETTE 50 mg/850 mg | film-coated tablets | 50mg/850mg | GEDEON RICHTER ROMANIA S.A. | ROMANIA | 1424 6 | 2022 |
| COMBINATIONS (SITAGLIPTINUM+ METFORMINUM) | JUZIMETTE 50 mg/1000 mg | film-coated tablets | 50mg/1000mg | GEDEON RICHTER ROMANIA S.A. | ROMANIA | 1424 7 | 2022 |
| COMBINATIONS (TAFLUPROSTUM+ TIMOLOLUM) | TAPTIQOM 15 micrograms/ml + 5 mg/ml | eye drops, solution in single dose recipient | 15micrograms/ ml + 5mg/ml | SANTEN OY | FINLAND | 1424 5 | 2022 |

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| COMBINATIONS (TRAVOPROSTUM+ TIMOLOLUM) | TRAVOPROST/ TIMOLOL ZENTIVA 40 micrograms/ml+5 mg/ml | eye drops, solution | 40micrograms/ ml+5mg/ml | ZENTIVA, K.S. | THE CZECH REPUBLIC | 1436 9 | 2022 |
| COMBINATIONS (VILDAGLIPTINUM+ METFORMINUM) | IPINZAN 50 mg/850 mg | film-coated tablets | 50 mg/850 mg | ZENTIVA K.S. | THE CZECH REPUBLIC | 1425 1 | 2022 |
| COMBINATIONS (VILDAGLIPTINUM+ METFORMINUM) | IPINZAN 50 mg/1000 mg | film-coated tablets | 50 mg/ 1000 mg | ZENTIVA K.S. | THE CZECH REPUBLIC | 1425 2 | 2022 |
| CYCLOPHOSPHAMIDUM | CICLOFOSFAMIDA DR. REDDY'S 500 mg/ml | concentrate for solution for injection/infusion | 500mg/ml | DR. REDDY'S LABORATORIES ROMANIA S.R.L. | ROMANIA | 1435 0 | 2022 |
| CYCLOPHOSPHAMIDUM | CICLOFOSFAMIDA DR. REDDY'S 1000 mg/2ml | concentrate for solution for injection/infusion | 1000mg/2ml | DR. REDDY'S LABORATORIES ROMANIA S.R.L. | ROMANIA | 1435 1 | 2022 |
| CYCLOPHOSPHAMIDUM | CICLOFOSFAMIDA DR. REDDY'S 2000 mg/4ml | concentrate for solution for injection/infusion | 2000mg/4ml | DR. REDDY'S LABORATORIES ROMANIA S.R.L. | ROMANIA | 1435 2 | 2022 |
| DEFERASIROXUM | DEFLOXOL 90 mg | film-coated tablets | 90mg | EGIS PARMACEUTICALS PLC | HUNGARY | 1430 7 | 2022 |
| DEFERASIROXUM | DEFLOXOL 180 mg | film-coated tablets | 180mg | EGIS PARMACEUTICALS PLC | HUNGARY | 1430 8 | 2022 |
| DEFERASIROXUM | DEFLOXOL 360 mg | film-coated tablets | 360mg | EGIS PARMACEUTICALS PLC | HUNGARY | 1430 9 | 2022 |
| DEXKETOPROFENUM | FENODEX 12.5 mg | film-coated tablets | 12.5mg | MEDOCHEMIE LTD. | CYPRUS | 1429 6 | 2022 |

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|--------------------|---|------------------------------------|-----------------|---------------------------------|----------|-----------|------|
| DEXKETOPROFENUM | FENODEX 25 mg | film-coated tablets | 25mg | MEDOCHEMIE LTD. | CYPRUS | 1429 7 | 2022 |
| DEXTROMETHORPHANUM | DINAREX 1.5 mg/ml | syrup | 1.5mg/ml | MEDOCHEMIE ROMANIA SRL | ROMANIA | 1434 2 | 2022 |
| DIVERSE | APA PENTRU PREPARATE INJECTABILE B. BRAUN PLASCO | solvent for parenteral preparation | | B. BRAUN MELSUNGEN AG | GERMANY | 1437 3 | 2022 |
| ETORICOXIBUM | ROTICOX 30 mg | film-coated tablets | 30mg | KRKA, D.D., NOVO MESTO | SLOVENIA | 1436 1 | 2022 |
| ETORICOXIBUM | ROTICOX 60 mg | film-coated tablets | 60mg | KRKA, D.D., NOVO MESTO | SLOVENIA | 1436 2 | 2022 |
| ETORICOXIBUM | ROTICOX 90 mg | film-coated tablets | 90mg | KRKA, D.D., NOVO MESTO | SLOVENIA | 1436 3 | 2022 |
| ETORICOXIBUM | ROTICOX 120 mg | film-coated tablets | 120mg | KRKA, D.D., NOVO MESTO | SLOVENIA | 1436 4 | 2022 |
| FENTANYLUM | FENTANIL KALCEKS 50 micrograms/ml | solution for injection | 50micrograms/ml | AKCIJU SABIEDRIBA KALCEKS | LETONIA | 1435 4 | 2022 |
| FINGOLIMODUM | FINGOLIMOD RICHTER 0.5 mg | capsules | 0.5mg | GEDEON RICHTER PLC. | HUNGARY | 1433 1 | 2022 |
| FLURBIPROFENUM | STREPSILS INTENSIV PORTOCALE SI MENTOL FARA ZAHAR 8.75 mg | pills | 8.75mg | RECKITT BENCKISER (ROMANIA) SRL | ROMANIA | 1424 1 | 2022 |
| FLURBIPROFENUM | STREPSILS INTENSIV FARA ZAHAR 8.75 mg | pills | 8.75mg | RECKITT BENCKISER (ROMANIA) SRL | ROMANIA | 1424 2 | 2022 |

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| FULVESTRANTUM | FALVAX 250 mg | solution for injection in pre-filled syringe | 250mg | DR. REDDY'S LABORATORIES ROMANIA S.R.L. | ROMANIA | 14270 | 2022 |
| HALOPERIDOLUM | HALOPERIDOL LAROPHARM 0.5 mg | tablets | 0.5mg | LAROPHARM S.R.L. | ROMANIA | 14273 | 2022 |
| IBUPROFENUM | IBUVALEN 400 mg | capsules | 400mg | POLISANO PHARMACEUTICALS S.A. | ROMANIA | 14371 | 2022 |
| IBUPROFENUM | IBUPROFEN US PHARMACIA 200 mg | film-coated tablets | 200mg | US PHARMACIA SP. Z O.O. | POLAND | 14367 | 2022 |
| IBUPROFENUM | IBUPROFEN US PHARMACIA 400 mg | film-coated tablets | 400mg | US PHARMACIA SP. Z O.O. | POLAND | 14368 | 2022 |
| IMUNOGLOBULINA ANTI-LIMFOCITE (DE CAL) | ATGAM 50 mg/ml | concentrate for solution for infusion | 50mg/ml | PFIZER EUROPE MA EEIG | BELGIUM | 14292 | 2022 |
| IVABRADINUM | BIXEBRA 5 mg | film-coated tablets | 5mg | KRKA, D.D., NOVO MESTO | SLOVENIA | 14340 | 2022 |
| IVABRADINUM | BIXEBRA 7.5 mg | film-coated tablets | 7.5mg | KRKA, D.D., NOVO MESTO | SLOVENIA | 14341 | 2022 |
| LENALIDOMIDUM | LENALIDOMIDA TEVA 5 mg | capsules | 5mg | TEVA B.V. | HOLLAND | 14288 | 2022 |
| LENALIDOMIDUM | LENALIDOMIDA TEVA 10 mg | capsules | 10mg | TEVA B.V. | HOLLAND | 14289 | 2022 |
| LENALIDOMIDUM | LENALIDOMIDA TEVA 15 mg | capsules | 15mg | TEVA B.V. | HOLLAND | 14290 | 2022 |
| LENALIDOMIDUM | LENALIDOMIDA TEVA 20 mg | capsules | 20mg | TEVA B.V. | HOLLAND | 14291 | 2022 |
| MELOXICAMUM | MELOXICAM LAROPHARM 7.5 mg | tablets | 7.5mg | LAROPHARM SRL | ROMANIA | 14287 | 2022 |

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| MEROPENEMUM | MEROPENEM ANTIBIOTICE 500 mg | powder for solution for injection/infusion | 500mg | ANTIBIOTICE S.A. | ROMANIA | 1424 8 | 2022 |
| MEROPENEMUM | MEROPENEM ANTIBIOTICE 1 g | powder for solution for injection/infusion | 1g | ANTIBIOTICE S.A. | ROMANIA | 1424 9 | 2022 |
| METHOTREXATUM | NAMAXIR 7.5 mg | solution for injection in pre- filled syringe | 7.5mg | TEVA B.V. | HOLLAND | 1430 2 | 2022 |
| METHOTREXATUM | NAMAXIR 10 mg | solution for injection in pre- filled syringe | 10mg | TEVA B.V. | HOLLAND | 1430 3 | 2022 |
| METHOTREXATUM | NAMAXIR 15 mg | solution for injection in pre- filled syringe | 15mg | TEVA B.V. | HOLLAND | 1430 4 | 2022 |
| METHOTREXATUM | NAMAXIR 20 mg | solution for injection in pre- filled syringe | 20mg | TEVA B.V. | HOLLAND | 1430 5 | 2022 |
| METHOTREXATUM | NAMAXIR 25 mg | solution for injection in pre- filled syringe | 25mg | TEVA B.V. | HOLLAND | 1430 6 | 2022 |
| METHOTREXATUM | METORTHTRIT 10 mg/ml | solution for injection in pre- filled syringe | 10mg/ml | ROMPHARM COMPANY S.R.L. | ROMANIA | 1425 6 | 2022 |
| METOCLOPRAMIDUM | METOCLOPRAMID HAMELN 5 mg/ml | solution for injection | 5 mg/ml | HAMELN PHARMA GMBH | GERMANY | 1426 9 | 2022 |
| MICAFUNGINUM | MICAFUNGIN ROMPHARM 100 mg | powder for concentrate for solution for infusion | 100mg | ROMPHARM COMPANY S.R.L. | ROMANIA | 1437 6 | 2022 |

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| MOMETASONUM | FUROAT DE MOMETAZONA AMRING 50 micrograms/dose | nasal spray, suspension | 50micrograms/ dose | AMRING FARMA S.R.L. | ROMANIA | 1428 3 | 2022 |
| MOXIFLOXACINUM | AVELOX 400 mg | film-coated tablets | 400mg | BAYER AG | GERMANY | 1428 5 | 2022 |
| MOXIFLOXACINUM | AVELOX 400 mg/250 ml | solution for infusion | 400mg/250ml | BAYER AG | GERMANY | 1428 6 | 2022 |
| NATRII CROMOGLICAS | LECROLYN 40 mg/ml | eye drops, solution | 40mg/ml | SANTEN OY | FINLAND | 1432 4 | 2022 |
| NICOTINUM | NICORETTE BERRYMINT 1 mg/spray | oromucosal spray, solution | 1mg/spray | MCNEIL AB | SWEDEN | 1432 0 | 2022 |
| ONDANSETRONUM | ONDASAN 2 mg/ml | solution for injection | 2mg/ml | MESFARMA SRL | ROMANIA | 1429 5 | 2022 |
| PARACETAMOLUM | PARACETAMOL TEVA 1000 mg | tablets | 1000mg | TEVA PHARMACEUTICA LS S.R.L. | ROMANIA | 1429 9 | 2022 |
| PARACETAMOLUM | PARACETAMOL RAPID TEVA 500 mg | film-coated tablets | 500mg | TEVA PHARMACEUTICA LS S.R.L. | ROMANIA | 1429 8 | 2022 |
| PAZOPANIBUM | PAZOPANIB ZENTIVA 200 mg | film-coated tablets | 200mg | ZENTIVA K.S. | THE CZECH REPUBLIC | 1430 0 | 2022 |
| PAZOPANIBUM | PAZOPANIB ZENTIVA 400 mg | film-coated tablets | 400mg | ZENTIVA K.S. | THE CZECH REPUBLIC | 1430 1 | 2022 |
| PAZOPANIBUM | PYZYPI 200 mg | film-coated tablets | 200mg | STADA M&D S.R.L. | ROMANIA | 1436 5 | 2022 |
| PAZOPANIBUM | PYZYPI 400 mg | film-coated tablets | 400mg | STADA M&D S.R.L. | ROMANIA | 1436 6 | 2022 |

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| PEMETREXEDUM | PEMETREXED ZENTIVA 10 mg/ml | solution for infusion | 10mg/ml | ZENTIVA K.S. | THE CZECH REPUBLIC | 1428 2 | 2022 |
| PLANTE | CANEPHRON FORTE | lozenges | | BIONORICA SE | GERMANY | 1424 0 | 2022 |
| PLANTE | MUCOPLANT IEDERA FORTE 33 mg | syrup | 33mg | DR. THEISS NATURWAREN GMBH | GERMANY | 1437 4 | 2022 |
| PLANTE (CIMBRU+NALBA MARE) | BRONCHOSTOP DUO | oral gum | | KWIZDA PHARMA GMBH | AUSTRIA | 1423 8 | 2022 |
| PLANTE (CIMBRU+NALBA MARE) | BRONCHOSTOP | syrup | | KWIZDA PHARMA GMBH | AUSTRIA | 1423 7 | 2022 |
| PLANTE (LEVANTICA) | LILANDOR 80 mg | soft capsules | 80mg | DR. WILLMAR SCHWABE GMBH & CO. KG | GERMANY | 1433 4 | 2022 |
| PROGESTERONUM | CYCLOVITA 400 mg | ovules | 400mg | GEDEON RICHTER ROMANIA S.A. | ROMANIA | 1427 8 | 2022 |
| PROPOFOLUM | PROPOFOL ROMPHARM 10mg/ml | emulsion for injection/infusion | 10mg/ml | ROMPHARM COMPANY S.R.L. | ROMANIA | 1429 3 | 2022 |
| RIVAROXABANUM | XIMPROVE 10 mg | film-coated tablets | 10mg | DR. REDDY'S LABORATORIES ROMANIA S.R.L. | ROMANIA | 1425 3 | 2022 |
| RIVAROXABANUM | XIMPROVE 15 mg | film-coated tablets | 15mg | DR. REDDY'S LABORATORIES ROMANIA S.R.L. | ROMANIA | 1425 4 | 2022 |
| RIVAROXABANUM | XIMPROVE 20 mg | film-coated tablets | 20mg | DR. REDDY'S LABORATORIES ROMANIA S.R.L. | ROMANIA | 1425 5 | 2022 |

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| SITAGLIPTINUM | JIMANDIN 25 mg | film-coated tablets | 25mg | MEDOCHEMIE LTD. | CYPRUS | 1438 0 | 2022 |
| SITAGLIPTINUM | JIMANDIN 50 mg | film-coated tablets | 50mg | MEDOCHEMIE LTD. | CYPRUS | 1438 1 | 2022 |
| SITAGLIPTINUM | JIMANDIN 100 mg | film-coated tablets | 100mg | MEDOCHEMIE LTD. | CYPRUS | 1438 2 | 2022 |
| SITAGLIPTINUM | JAZETA 100 mg | film-coated tablets | 100mg | ZENTIVA K.S. | THE CZECH REPUBLIC | 1426 4 | 2022 |
| SOLIFENACINUM SUCCINATE | VESISTAD 5 mg | film-coated tablets | 5mg | STADA M&D S.R.L. | ROMANIA | 1431 7 | 2022 |
| SOLIFENACINUM SUCCINATE | VESISTAD 10 mg | film-coated tablets | 10mg | STADA M&D S.R.L. | ROMANIA | 1431 8 | 2022 |
| TADALAFILUM | TADALAFIL ARISTO PHARMA 5 mg | film-coated tablets | 5mg | ARISTO PHARMA GMBH | | 1425 9 | 2022 |
| TADALAFILUM | TADALAFIL ARISTO PHARMA 10 mg | film-coated tablets | 10mg | ARISTO PHARMA GMBH | | 1426 0 | 2022 |
| TADALAFILUM | TADALAFIL ARISTO PHARMA 20 mg | film-coated tablets | 20mg | ARISTO PHARMA GMBH | | 1426 1 | 2022 |
| TIGECYCLINUM | TIGECICLINA MYLAN 50 mg | powder for solution for infusion | 50mg | MYLAN PHARMACEUTICALS LIMITED | IRELAND | 1433 0 | 2022 |
| TIGECYCLINUM | TIGECICLINA ROMPHARM 50 mg | powder for solution for infusion | 50mg | ROMPHARM COMPANY S.R.L. | ROMANIA | 1437 5 | 2022 |
| TOBRAMYCINUM | TOBRAMICINA SUN 300 mg | nebuliser solution | 300mg | SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V. | HOLLAND | 1425 0 | 2022 |

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| TOXINA BOTULINICA DE TIP A | LETYBO 50 UNITATI | powder for solution for injection | 50 units | CROMA PHARMA GMBH | AUSTRIA | 14329 | 2022 |
| VANCOMYCINUM | VANCOMICINA APHAPHARMA 500 mg | powder for concentrate for solution for infusion | 500mg | APTA MEDICA INTERNACIONAL D.O.O | SLOVENIA | 14312 | 2022 |
| VANCOMYCINUM | VANCOMICINA APHAPHARMA 1000 mg | powder for concentrate for solution for infusion | 1000mg | APTA MEDICA INTERNACIONAL D.O.O | SLOVENIA | 14313 | 2022 |
| VILDAGLIPTINUM | DALMEVIN 50 mg | tablets | 50mg | MEDOCHEMIE LTD. | CYPRUS | 14316 | 2022 |
| XYLOMETAZOLINUM | SNUP 0.5 mg/ml | nasal spray, solution | 0.5mg/ml | STADA M&D SRL | ROMANIA | 14235 | 2022 |
| XYLOMETAZOLINUM | SNUP 1mg/ml | nasal spray, solution | 1mg/ml | STADA M&D SRL | ROMANIA | 14236 | 2022 |

Medicinal products authorised through centralised procedure, performed at the level of the European Medicines Agency (EMA), notified for marketing in Romania during the 1st quarter of 2022

| INN | Trade name | Pharmaceutical form | Strength | MAH | Holding country | MA no. | |
|---------------|-----------------------|---------------------------------------|----------|----------------|-----------------|--------|------|
| ANIFROLUMABUM | SAPHNELO 300 mg | concentrate for solution for infusion | 150mg/ml | ASTRAZENECA AB | SWEDEN | 1623 | 2022 |
| APIXABANUM | APIXABAN STADA 5 mg | film-coated tablets | 5mg | STADA M&D SRL | ROMANIA | 14384 | 2022 |
| APIXABANUM | APIXABAN STADA 2.5 mg | film-coated tablets | 2.5mg | STADA M&D SRL | ROMANIA | 14383 | 2022 |

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| GLUCARPIDAZUM | VORAXAZE 1000 UNITATI | powder for solution for injection | 1000units | SERB SAS | FRANCE | 1586 | 2022 |
| PF-07321332+RITONAVIRUM | PAXLOVID 150 mg+100 mg | film-coated tablets | 150mg+100mg | PFIZER EUROPE MA EEIG | BELGIUM | 1625 | 2022 |
| RISPERIDONUM | OKEDI 75 mg | powder and solvent for suspension for injection, prolonged- release | 75mg | LABORATORIOS FARMACEUTICOS ROVI S.A. | SPAIN | 1621 | 2022 |
| RISPERIDONUM | OKEDI 100 mg | powder and solvent for suspension for injection, prolonged- release | 100mg | LABORATORIOS FARMACEUTICOS ROVI S.A. | SPAIN | 1621 | 2022 |
| RURIOCTOCOG ALFA PEGOL | ADYNOVI 3000 IU/5 ml | powder and solvent for solution for injection | 3000UI/5ml | BAXALTA INNOVATIONS GMBH | AUSTRIA | 1247 | 2022 |
| SEMAGLUTIDUM | WEGOVI 0.25 mg | solution for injection in pre-filled pen | 0.25mg | NOVO NORDISK A/S | DENMARK | 1608 | 2022 |
| SEMAGLUTIDUM | WEGOVI 0.5 mg | solution for injection in pre-filled pen | 0.5mg | NOVO NORDISK A/S | DENMARK | 1608 | 2022 |
| SEMAGLUTIDUM | WEGOVI 1 mg | solution for injection in pre-filled pen | 1mg | NOVO NORDISK A/S | DENMARK | 1608 | 2022 |

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| SEMAGLUTIDUM | WEGOVY 1.7 mg | solution for injection in pre-filled pen | 1.7mg | NOVO NORDISK A/S | DENMARK | 1608 | 2022 |
| SEMAGLUTIDUM | WEGOVY 2.4 mg | solution for injection in pre-filled pen | 2.4mg | NOVO NORDISK A/S | DENMARK | 1608 | 2022 |
| SEMAGLUTIDUM | WEGOVY 0.25 mg FLEXTOUCH | solution for injection in pre-filled pen | 0.25mg | NOVO NORDISK A/S | DENMARK | 1608 | 2022 |
| SEMAGLUTIDUM | WEGOVY 0.5 mg FLEXTOUCH | solution for injection in pre-filled pen | 0.5mg | NOVO NORDISK A/S | DENMARK | 1608 | 2022 |
| SEMAGLUTIDUM | WEGOVY 1 mg FLEXTOUCH | solution for injection in pre-filled pen | 1mg | NOVO NORDISK A/S | DENMARK | 1608 | 2022 |
| SEMAGLUTIDUM | WEGOVY 1.7 mg FLEXTOUCH | solution for injection in pre-filled pen | 1.7mg | NOVO NORDISK A/S | DENMARK | 1608 | 2022 |
| SEMAGLUTIDUM | WEGOVY 2.4 mg FLEXTOUCH | solution for injection in pre-filled pen | 2.4mg | NOVO NORDISK A/S | DENMARK | 1608 | 2022 |
| SOMATROGONUM | NGENLA 24 mg | solution for injection in pre-filled pen | 24 mg/1.2 ml | PFIZER EUROPE MA EEIG | BELGIUM | 1617 | 2022 |
| SOMATROGONUM | NGENLA 60 mg | solution for injection in pre-filled pen | 60 mg/1.2 ml | PFIZER EUROPE MA EEIG | BELGIUM | 1617 | 2022 |
| SOTORASIB | LUMYKRAS 120 mg | film-coated tablets | 120mg | AMGEN EUROPE B.V. | THE NETHERLANDS | 1603 | 2022 |

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| TIXAGEVIMAB+CILGAVIMAB | EVUSHELD 150 mg+150 mg | solution for injection | 150mg+150mg | ASTRAZENECA AB | SWEDEN | 1651 | 2022 |
| VACC PNEUMOCOCIC POLIZAHARIDIC CONJ. 20- VALENT ADS | APEXXNAR | suspension for injection in pre-filled syringe | | PFIZER EUROPE MA EEIG | BELGIUM | 1612 | 2022 |