

ROMANIA

Newsletter

Year 23, No. 1 (89), 1st quarter of 2021

National Agency For Medicines and Medical Devices of Romania

Medicinal product batches recalled during the 1st quarter of 2021

Applications for marketing authorisation/marketing authorisation renewal received during the 4th quarter of 2020

Medicinal products authorised for marketing by the NAMMDR during the 4th quarter of 2020

Medicinal products authorised through centralised procedure, performed at the level of the European Medicines Agency (EMA), notified for marketing in Romania during the 4th quarter of 2020

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ISSN 1583-347X

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Medicinal product batches recalled during the 1st quarter of 2021

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	Cefotax 1 g	im/iv powder + solvent for solution for injection	1 g	cefotaxime	Felsin Farm SRL Romania/EIPICO Med SRL, Romania	2004464	voluntary recall from the market, following the identification of a noncompliance related to the expiry date imprinted on the solvent of 3416 ct out of the total of 20612 ct (imprinted date - 07.2021/real date- 07.2022)	Voluntary recall and destruction	22.02.2021
2	Ranitidina 150 mg	tablets	150 mg	ranitidine	Magistra C&C SRL, Romania	all batches	recall at pharmacy level of all batches, following suspension of all valid MAs for medicinal products containing ranitidine (in line with European Commission Decision C-2020 8429/24.11.2020)	Voluntary recall and destruction	04.03.2021
3	Ranitidin 150 mg	film-coated tablets	150 mg	ranitidine	Arena Group SA	all batches	recall at pharmacy level of all batches, following suspension of all valid MAs for medicinal products containing ranitidine (in line with European Commission Decision C-2020	Voluntary recall and destruction	04.03.2021

							8429/24.11.2020)		
4	Ranitidin Arena 150 mg	film-coated tablets	150 mg	ranitidine	Arena Group SA	all batches	recall at pharmacy level of all batches, following suspension of all valid MAs for medicinal products containing ranitidine (in line with European Commission Decision C-2020 8429/24.11.2020)	Recall and destruction	04.03.2021
5	Ranitidina Arena 75 mg	capsules	75 mg	ranitidine	Arena Group SA	all batches	recall at pharmacy level of all batches, following suspension of all valid MAs for medicinal products containing ranitidine (in line with European Commission Decision C-2020 8429/24.11.2020)	Recall and destruction	04.03.2021
6	Ranitidina Arena 300 mg	capsules	300 mg	ranitidine	Arena Group SA	all batches	recall at pharmacy level of all batches, following suspension of all valid MAs for medicinal products containing ranitidine (in line with European Commission Decision C-2020 8429/24.11.2020)	Recall and destruction	04.03.2021

							8429/24.11.2020)		
7	Ranitidina Helcor 150 mg	film-coated tablets	150 mg	ranitidine	AC Helcor Pharma SRL	all batches	recall at pharmacy level of all batches, following suspension of all valid MAs for medicinal products containing ranitidine (in line with European Commission Decision C-2020 8429/24.11.2020)	Recall and destruction	04.03.2021
8	Ranitidina Helcor 75 mg	film-coated tablets	75 mg	ranitidine	AC Helcor Pharma SRL	all batches	recall at pharmacy level of all batches, following suspension of all valid MAs for medicinal products containing ranitidine (in line with European Commission Decision C-2020 8429/24.11.2020)	Recall and destruction	04.03.2021
9	Nitroxolina- MIP 250 mg	soft capsules	250 mg	nitroxoline	Chephasar Chem.- Pharm.Fabrik GmbH, GERMANY/Mip Pharma GmbH, Germany	304150 9, 305370 9	voluntary recall from the market as a precautionary measure, due to decrease of a limit value for qualification of the active substance	Voluntary recall and destruction	10.03.2021

**Applications for marketing authorisation/marketing authorisation renewal
received during the 4th quarter of 2020**

In the 4th quarter of 2020, 12 marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

ATC CODE
A06 - DRUGS FOR CONSTIPATION
A06 - DRUGS FOR CONSTIPATION
B06 – OTHER HEMATOLOGICAL AGENTS
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
P01 - ANTIPROTOZOALS
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
B01 - ANTITHROMBOTIC AGENTS
G03 - SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

Medicinal products authorised for marketing by the NAMMDR during the 4th quarter of 2020

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
AMIODARONUM	AMIODARONA ACCORD 30 mg/ml	concentrate for solution for injection/infusion	30mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	1361 7	2020
ARIPIPRAZOLUM	ARICOGAN 10 mg	tablets	10mg	G.L. PHARMA GMBH	AUSTRIA	1351 0	2020
ARIPIPRAZOLUM	ARICOGAN 15 mg	tablets	15mg	G.L. PHARMA GMBH	AUSTRIA	1351 1	2020
ATROPINUM	SULFAT DE ATROPINA ACCORD 1 mg/ml	solution for injection in pre- filled syringe	1mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	1359 3	2020
AZACITIDINUM	AZACITIDINA SANDOZ 25 mg/ml	powder for suspension for injection	25mg/ml	SANDOZ S.R.L.	ROMANIA	1351 6	2020
BENDAMUSTINUM	RIBOVACT 2.5 mg/ml	powder for concentrate for solution for infusion	2.5mg/ml	ASTELLAS PHARMA GMBH	GERMANY	1352 1	2020
BETAHISTINUM	BETAHISTINA DICLORHIDRAT AUROBINDO 8 mg	tablets	8mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	1359 9	2020
BETAHISTINUM	BETAHISTINA DICLORHIDRAT AUROBINDO 16 mg	tablets	16mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	1360 0	2020

BETAHISTINUM	BETAHISTINA DICLORHIDRAT AUROBINDO 24 mg	tablets	24mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	1360 1	2020
BIMATOPROSTUM	BIMAGAN 0.1 mg/ml	eye drops, solution	0.1mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	1357 6	2020
BRINZOLAMIDUM	BRINZOLAMIDA ACCORD 10 mg/ml	eye drops, suspension	10mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	1357 7	2020
BUSULFANUM	BUSULFAN ACCORD 6 mg/ml	concentrate for solution for infusion	6mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	1358 5	2020
CALCIFEDIOLUM	HIDROFEROL 0.266 mg	soft capsules	0.266mg	FAES FARMA S.A.	SPAIN	1352 7	2020
CANDESARTANUM CILEXETIL	CANDESARTAN ATB 8 mg	tablets	8mg	ANTIBIOTICE SA	ROMANIA	1355 3	2020
CANDESARTANUM CILEXETIL	CANDESARTAN ATB 16 mg	tablets	16mg	ANTIBIOTICE SA	ROMANIA	1355 4	2020
CEFUROXIMUM	CEFUROXIMA-MIP 750 mg	powder for solution for injection/infusion	750mg	MIP PHARMA GMBH	GERMANY	1353 6	2020
CEFUROXIMUM	CEFUROXIMA-MIP 1.5 g	powder for solution for injection/infusion	1.5g	MIP PHARMA GMBH	GERMANY	1353 7	2020
CELECOXIBUM	ALGOXIB 100 mg	capsules	100mg	ZENTIVA K.S.	THE CZECH REPUBLIC	1361 4	2020
CELECOXIBUM	ALGOXIB 200 mg	capsules	200mg	ZENTIVA K.S.	THE CZECH REPUBLIC	1361 5	2020

COMBINATIONS	FASCONAL	tablets		GEDEON RICHTER ROMANIA S.A.	ROMANIA	1351 5	2020
COMBINATIONS	STREPSILS CU AROMA DE PRUNE	pills	0.6mg/ 1.2mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	1356 2	2020
COMBINATIONS	STREPSILS EUCALIPT	pills	0.6mg/ 1.2mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	1356 3	2020
COMBINATIONS	DICARBOCALM CU AROMA DE COACAZE NEGRE 351.9 mg/400 mg	oral suspension, sachet	351.9mg/ 400mg	SANOFI ROMANIA SRL	ROMANIA	1356 0	2020
COMBINATIONS	DICARBOCALM CU AROMA DE LAMAIE 351.9 mg/400 mg	oral suspension, sachet	351.9mg/ 400mg	SANOFI ROMANIA SRL	ROMANIA	1356 1	2020
COMBINATIONS	CALCIU COLECALCIFEROL BERES 600 mg/800 UI	film-coated tablets	600mg/ 800 IU	BERES PHARMACEUTIC ALS LTD.	HUNGARY	1360 5	2020
COMBINATIONS (NETILMICINUM + DEXAMETHASONUM)	DEXAMETAZONA/ NETILMICINA NEWLINE PHARMA 3 mg/ml+1 mg/ml	eye gel in single- dose container	3mg/ml+ 1mg/ml	NEWLINE PHARMA, S.L.	SPAIN	1352 3	2020
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	AMLODIPINA/VALSARTAN AUROBINDO 5 mg/80 mg	film-coated tablets	5mg/80mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	1361 1	2020
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	AMLODIPINA/VALSARTAN AUROBINDO 5 mg/160 mg	film-coated tablets	5mg/160mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	1361 2	2020

COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	AMLODIPINA/VALSARTAN AUROBINDO 10 mg/160 mg	film-coated tablets	10mg/ 160mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	1361 3	2020
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	AMLODIPINA/VALSARTAN STADA 5 mg/80 mg	film-coated tablets	5mg/80mg	STADA M&D S.R.L.	ROMANIA	1363 1	2020
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	AMLODIPINA/VALSARTAN STADA 5 mg/160 mg	film-coated tablets	5mg/ 160mg	STADA M&D S.R.L.	ROMANIA	1363 2	2020
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	AMLODIPINA/VALSARTAN STADA 10 mg/160 mg	film-coated tablets	10mg/ 160mg	STADA M&D S.R.L.	ROMANIA	1363 3	2020
COMBINATIONS (BIMATOPROSTUM + TIMOLOLUM)	BIMATOPROST/TIMOLOL ZENTIVA 0.3 mg/5 mg/ml	eye drops, solution	0.3mg/ 5mg/ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	1357 8	2020
COMBINATIONS (CHLORHEXIDINUM + LIDOCAINUM)	CEBANGIN MENTOL 2 mg/0.5 mg/ml	oromucosal spray, solution	2mg/ 0.5mg/ml	CEBIS INTERNATIONA L SRL ROMANIA	ROMANIA	1362 3	2020
COMBINATIONS (CHLORHEXIDINUM + LIDOCAINUM)	CEBANGIN LAMAIE 2 mg/0.5 mg/ml	oromucosal spray, solution	2mg/ 0.5mg/ml	CEBIS INTERNATIONA L SRL ROMANIA	ROMANIA	1362 4	2020
COMBINATIONS (LEVODOPUM+ BENSERAZIDUM)	MADOPAR 200mg/50mg	tablets	200mg+ 50mg	ROCHE ROMANIA S.R.L.	ROMANIA	1358 9	2020
COMBINATIONS (LEVODOPUM+ BENSERAZIDUM)	MADOPAR HBS	modified-release capsules	100mg+ 25mg	ROCHE ROMANIA S.R.L.	ROMANIA	1359 0	2020

COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	TRIGELAN 50 mg/12.5 mg/200 mg	film-coated tablets	50mg/ 12.5mg/ 200mg	G.L. PHARMA GMBH	AUSTRIA	1362 7	2020
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	TRIGELAN 100 mg/25 mg/200 mg	film-coated tablets	100mg/ 25mg/ 200mg	G.L. PHARMA GMBH	AUSTRIA	1362 8	2020
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	TRIGELAN 150 mg/37.5 mg/200 mg	film-coated tablets	150mg/ 37.5mg/ 200mg	G.L. PHARMA GMBH	AUSTRIA	1362 9	2020
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	TRIGELAN 200 mg/50 mg/200 mg	film-coated tablets	200mg/ 50mg/ 200mg	G.L. PHARMA GMBH	AUSTRIA	1363 0	2020
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LECIGON 20 mg/5 mg/20 mg/ml	intestinal gel	20mg/5mg/20 mg/ml	LABSOR PHARMACEUTIC ALS AB	SWEDEN	1358 4	2020
COMBINATIONS (OXICODONUM+ NALOXONUM)	OXICODONA/NALOXONA SANDOZ 5 mg/2.5 mg	prolonged-release tablets	5mg/ 2.5mg	SANDOZ S.R.L.	ROMANIA	1361 8	2020
COMBINATIONS (OXICODONUM+ NALOXONUM)	OXICODONA/NALOXONA SANDOZ 10 mg/5 mg	prolonged-release tablets	10mg/5mg	SANDOZ S.R.L.	ROMANIA	1361 9	2020
COMBINATIONS (OXICODONUM+ NALOXONUM)	OXICODONA/NALOXONA SANDOZ 20 mg/10 mg	prolonged-release tablets	20mg/ 10mg	SANDOZ S.R.L.	ROMANIA	1362 0	2020

COMBINATIONS (OXICODONUM+ NALOXONUM)	OXICODONA/NALOXONA SANDOZ 30 mg/15 mg	prolonged-release tablets	30mg/ 15mg	SANDOZ S.R.L.	ROMANIA	1362 1	2020
COMBINATIONS (OXICODONUM+ NALOXONUM)	OXICODONA/NALOXONA SANDOZ 40 mg/20 mg	prolonged-release tablets	40mg/ 20mg	SANDOZ S.R.L.	ROMANIA	1362 2	2020
COMBINATIONS (TOBRAMYCINUM+ DEXAMETHASONUM)	DEXATOBROM 3 mg+1 mg/ml	eye drops, suspension	3mg+ 1mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	1355 5	2020
COMBINATIONS (TROPICAMIDUM+ PHENYLEPHRINUM+ LIDOCAINUM)	MYDRANE 0.2 mg/ml+3.1 mg/ml+10 mg/ml	solution for injection	0.2mg/ml+ 3.1mg/ml+ 10mg/ml	LABORATOIRES THEA S.A.S.	FRANCE	1357 9	2020
DEXKETOPROFENUM	DEXKETOPROFEN TROMETAMOL SANDOZ 25 mg	film-coated tablets	25mg	SANDOZ S.R.L.	ROMANIA	1351 7	2020
DEXKETOPROFENUM	DEKENOR 25 mg	film-coated tablets	25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1352 5	2020
DICLOFENACUM	CLAFEN 11.6 mg/g	gel	11.6mg	ANTIBIOTICE S.A.	ROMANIA	1355 9	2020
DULOXETINUM	ONELAR 20 mg	gastroresistant capsules	20mg	MEDOCHEMIE LTD.	CYPRUS	1350 4	2020
DULOXETINUM	ONELAR 30 mg	gastroresistant capsules	30mg	MEDOCHEMIE LTD.	CYPRUS	1350 5	2020
DULOXETINUM	ONELAR 40 mg	gastroresistant capsules	40mg	MEDOCHEMIE LTD.	CYPRUS	1350 6	2020

DULOXETINUM	ONELAR 60 mg	gastroresistant capsules	60mg	MEDOCHEMIE LTD.	CYPRUS	1350 7	2020
DUTASTERIDUM	DUTASTERIDA ZENTIVA 0.5 mg	soft capsules	0.5mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	1353 5	2020
EXEMESTANUM	EXEMESTAN ACCORD 25 mg	film-coated tablets	25mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	1356 5	2020
FINGOLIMODUM	FINGOLIMOD TIEFENBACHER 0.5 mg	capsules	0.5mg	ALFRED E. TIEFENBACHER GMBH & CO. KG	GERMANY	1359 4	2020
FLUTICASONUM PROPIONAT	ARQUIST 125 micrograms	pressurised solution for inhalation	125 micrograms	AMRING FARMA SRL	ROMANIA	1353 0	2020
FLUTICASONUM PROPIONAT	ARQUIST 250 micrograms	pressurised solution for inhalation	250 micrograms	AMRING FARMA SRL	ROMANIA	1353 1	2020
FONDAPARINUX SODIUM	FONDAPARINA DR. REDDY'S 7.5 mg/0.6 ml	solution for injection in pre-filled syringe	7.5mg/0.6ml	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	1351 3	2020
FONDAPARINUX SODIUM	FONDAPARINA DR. REDDY'S 2.5 mg/0.5 ml	solution for injection in pre-filled syringe	2.5mg/0.5ml	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	1351 2	2020
FULVESTRANTUM	VASTALOMA 250 mg	solution for injection in pre-filled syringe	250mg	ALVOGEN PHARMA TRADING EUROPE EOOD	BULGARIA	1352 4	2020

FULVESTRANTUM	IMARSA 250 mg	solution for injection in pre-filled syringe	250mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	1358 6	2020
GEFITINIBUM	GEFITINIB POLISANO 250 mg	film-coated tablets	250mg	POLISANO PHARMACEUTICALS S.A.	ROMANIA	1362 5	2020
GLICLAZIDUM	GLYCLADA 90 mg	modified-release tablets	90mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1351 9	2020
HYDROCORTISONUM	HIDROCORTIZON ZENTIVA 19.6 mg/5 ml	solution for injection	19.6mg/5ml	ZENTIVA S.A.	ROMANIA	1360 8	2020
IBUPROFENUM	PADUDEN CU AROMA DE CAISE 20 mg/ml	oral suspension	20mg/ml	TERAPIA S.A.	ROMANIA	1357 5	2020
IBUPROFENUM	IBUPROFEN KABI 400 mg	solution for infusion	400mg	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	1359 2	2020
IBUPROFENUM	IBALGIN EXPRESS 200 mg	soft capsules	200mg	SANOFI ROMANIA S.R.L.	ROMANIA	1352 8	2020
IBUPROFENUM	IBALGIN EXPRESS 400 mg	soft capsules	400mg	SANOFI ROMANIA S.R.L.	ROMANIA	1352 9	2020
IMATINIBUM	IMATINIB SANDOZ 100 mg	film-coated tablets	100mg	SANDOZ S.R.L.	ROMANIA	1350 8	2020
IMATINIBUM	IMATINIB SANDOZ 400 mg	film-coated tablets	400mg	SANDOZ S.R.L.	ROMANIA	1350 9	2020

NORMAL IMMUNOGLOBULIN FOR INTRAMUSCULAR USE	PANZYGA 100 mg/ml	solution for infusion	100mg/ml	OCTAPHARMA (IP) SPRL	BELGIUM	1359 5	2020
IOBITRIDOLUM	XENETIX 300	solution for injection	300mg/ml	GUERBET	FRANCE	1355 6	2020
IOBITRIDOLUM	XENETIX 350	solution for injection	350mg/ml	GUERBET	FRANCE	1355 7	2020
ISOSORBIDI DINITRAS	ISOSORBID DINITRAT ARENA 10 mg	tablets	10mg	ARENA GROUP S.A.	ROMANIA	1359 1	2020
ITRACONAZOLUM	OMICRAL 100 mg	capsules	100mg	BAUSCH HEALTH IRELAND LIMITED	IRELAND	1351 4	2020
LIDOCAINUM	LIDIAQ 40 mg/g	cream	40mg/g	FERNDAL LABORATORIES LTD	IRELAND	1361 6	2020
LIDOCAINUM	LIDBREE 42 mg/ml gel cu cedare intrauterina	gel	42 mg/ml	GEDEON RICHTER ROMÂNIA S.A.	ROMANIA	1351 8	2020
LOPERAMIDUM	LOPREX 2 mg	capsules	2mg	LAROPHARM S.R.L.	ROMANIA	1355 8	2020
LOPINAVIRUM+ RITONAVIRUM	LOPINAVIR/RITONAVIR TERAPIA 200mg/50 mg	film-coated tablets	200mg/ 50mg	TERAPIA S.A.	ROMANIA	1360 4	2020
MEPIVACAINUM	MEPIVACAINA NORMOGEN 30 mg/ml	solution for injection	30mg/ml	LABORATORIOS NORMON, S.A.	SPAIN	1352 2	2020
MESALAZINUM	SALCROZINE 500 mg	gastroresistant tablets	500mg	FAES FARMA S.A.	SPAIN	1355 2	2020

METHADONUM	METHASAN 10 mg/ml	concentrate for oral solution	10mg/ml	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	1352 6	2020
MICAFUNGINUM	MICAFUNGIN ROMPHARM 50 mg	powder for solution for infusion	50mg	ROMPHARM COMPANY S.R.L.	ROMANIA	1356 4	2020
MIDAZOLAMUM	MIDAZOLAM HYPERICUM 5 mg/ml	solution for injection/infusion	5mg/ml	HYPERICUM S.R.L.	ROMANIA	1358 7	2020
MOXIFLOXACINUM	MOXIFLOXACINA VIOSER 400 mg/250 ml	solution for infusion	400mg/250ml	VIOSER S.A. PARENTERAL SOLUTIONS INDUSTRY	GREECE	1359 7	2020
NAFTIFINUM	VIDRIL 10 mg/ml	cutaneous solution	10mg/ml	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	1359 6	2020
NORFLOXACINUM	NORFLOXACINA ATB 400 mg	film-coated tablets	400mg	ANTIBIOTICE S.A.	ROMANIA	1354 1	2020
PALONOSETRONUM	PALONOSETRON TEVA 250 micrograms	solution for injection	250 micrograms	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	1360 6	2020
PALONOSETRONUM	PALONOSETRON STADA 250 micrograms	solution for injection	250 micrograms	STADA M&D SRL	ROMANIA	1360 3	2020
PARACETAMOLUM	PARACETAMOL HELCOR 500 mg	tablets	500mg	AC HELCOR PHARMA S.R.L.	ROMANIA	1358 8	2020
PREGABALINUM	SIRANALEN 75 mg	capsules	75mg	MEDOCHEMIE LTD.	CYPRUS	1358 0	2020

PREGABALINUM	SIRANALEN 150 mg	capsules	150mg	MEDOCHEMIE LTD.	CYPRUS	1358 1	2020
PREGABALINUM	SIRANALEN 300 mg	capsules	300mg	MEDOCHEMIE LTD.	CYPRUS	1358 2	2020
PROGESTERONUM	PROLUTEX 25 mg	solution for injection	25mg	IBSA FARMACEUTICI ITALY SRL	ITALY	1357 4	2020
HUMAN BLOOD PLASMA PROTEINS (BLOOD GROUPS A,B,AB,0)	OCTAPLASLG 45-70 mg/ml	solution for infusion	45-70mg/ml	OCTAPHARMA (IP) SPRL	BELGIUM	1360 2	2020
QUETIAPINUM	KETILEPT EP 50 mg	prolonged-release tablets	50mg	EGIS PHARMACEUTICALS PLC	HUNGARY	1354 2	2020
QUETIAPINUM	KETILEPT EP 150 mg	prolonged-release tablets	150mg	EGIS PHARMACEUTICALS PLC	HUNGARY	1354 3	2020
QUETIAPINUM	KETILEPT EP 200 mg	prolonged-release tablets	200mg	EGIS PHARMACEUTICALS PLC	HUNGARY	1354 4	2020
QUETIAPINUM	KETILEPT EP 300 mg	prolonged-release tablets	300mg	EGIS PHARMACEUTICALS PLC	HUNGARY	1354 5	2020
QUETIAPINUM	KETILEPT EP 400 mg	prolonged-release tablets	400mg	EGIS PHARMACEUTICALS PLC	HUNGARY	1354 6	2020
RAMIPRILUM	RAMIPRIL ATB 2.5 mg	tablets	2.5mg	ANTIBIOTICE S.A.	ROMANIA	1353 8	2020
RAMIPRILUM	RAMIPRIL ATB 5 mg	tablets	5mg	ANTIBIOTICE S.A.	ROMANIA	1353 9	2020

RAMIPRILUM	RAMIPRIL ATB 10 mg	tablets	10mg	ANTIBIOTICE S.A.	ROMANIA	1354 0	2020
RIVAROXABANUM	ROMBIDUX 10 mg	film-coated tablets	10mg	MERCK ROMANIA SRL	ROMANIA	1353 2	2020
RIVAROXABANUM	ROMBIDUX 15 mg	film-coated tablets	15mg	MERCK ROMANIA SRL	ROMANIA	1353 3	2020
RIVAROXABANUM	ROMBIDUX 20 mg	film-coated tablets	20mg	MERCK ROMANIA SRL	ROMANIA	1353 4	2020
SEVOFLURANUM	SEVO-ANESTERAN	inhalation vapours, liquid		ROMPHARM COMPANY S.R.L.	ROMANIA	1362 6	2020
SORAFENIBUM	SORAFENIB G.L. PHARMA 200 mg	film-coated tablets	200mg	G.L. PHARMA GMBH	AUSTRIA	1358 3	2020
SUNITINIBUM	ASIKREBA 12.5 mg	capsules	12.5mg	ZENTIVA K.S.	THE CZECH REPUBLIC	1357 0	2020
SUNITINIBUM	ASIKREBA 25 mg	capsules	25mg	ZENIVA K.S.	THE CZECH REPUBLIC	1357 1	2020
SUNITINIBUM	ASIKREBA 37.5 mg	capsules	37.5 mg	ZENIVA K.S.	THE CZECH REPUBLIC	1357 2	2020
SUNITINIBUM	ASIKREBA 50 mg	capsules	50 mg	ZENIVA K.S.	THE CZECH REPUBLIC	1357 3	2020
SUNITINIBUM	TEURLATA 12.5 mg	capsules	12.5mg	LOTUS SUPPORT SERVICES S.R.L.	ROMANIA	1356 6	2020
SUNITINIBUM	TEURLATA 25 mg	capsules	25mg	LOTUS SUPPORT SERVICES S.R.L.	ROMANIA	1356 7	2020
SUNITINIBUM	TEURLATA 37.5 mg	capsules	37.5mg	LOTUS SUPPORT SERVICES S.R.L.	ROMANIA	1356 8	2020

SUNITINIBUM	TEURLATA 50 mg	capsules	50mg	LOTUS SUPPORT SERVICES S.R.L.	ROMANIA	1356 9	2020
TERBINAFINUM	LAMITER CREMA 10 mg/g	cream	10mg/g	ROMPHARM COMPANY S.R.L.	ROMANIA	1360 7	2020
TERIPARATIDUM	TERIPARATID ALVOGEN 20 micrograms/80 microliters	solution for injection in pre- filled pen	20micrograms/ 80microliters	LABORMED PHARMA S.A.	ROMANIA	1352 0	2020
VINORELBINUM	VINORELBINA ACCORD 10 mg/ml	concentrate for solution for infusion	10mg/ml	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	1359 8	2020

Medicinal products authorised through centralised procedure, performed at the level of the European Medicines Agency (EMA), notified for marketing in Romania during the 4th quarter of 2020

INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
ACALABRUTINIBUM	CALQUENCE 100 mg	capsules	100mg	ASTRA ZENECA AB	SWEDEN	1479	2020
CABOTEGRAVIRUM	VOCABRIA 400 mg	prolonged-release suspension for injection	400mg	VIIV HEALTHCARE BV	THE NETHERLANDS	1481	2020
CABOTEGRAVIRUM	VOCABRIA 30 mg	tablets	30mg	VIIV HEALTHCARE BV	THE NETHERLANDS	1481	2020
CABOTEGRAVIRUM	VOCABRIA 600 mg	prolonged-release suspension for injection	600mg	VIIV HEALTHCARE BV	THE NETHERLANDS	1481	2020
COMBINATIONS (PERTUZUMABUM+ TRASTUZUMABUM)	PHESGO 1200 mg/600 mg	solution for injection	1200mg/600 mg	ROCHE REGISTRATION GMBH	GERMANY	1497	2020
COMBINATIONS (PERTUZUMABUM+ TRASTUZUMABUM)	PHESGO 600 mg/600 mg	solution for injection	600mg/600 mg	ROCHE REGISTRATION GMBH	GERMANY	1497	2020

COMBINATIONS (FORMOTEROLUM+ GLICOPIRONIUM+ BUDESONIDUM)	TRIXEO AEROSPHERE 5 micrograms/ 7.2 micrograms/ 160 micrograms	pressurised suspension for inhalation	5µg/7.2µg/ 160µg	ASTRAZENECA AB	SWEDEN	1498	2020
INCLISIRAN	LEQVIO 284 mg	solution for injection	189 mg/ml	NOVARTIS EUROPHARM LIMITED	IRELAND	1494	2020
LUMASIRANUM	OXLUMO 94.5 mg/0.5 ml	solution for injection	94.5mg/ 0.5ml	ALNYLAM NETHERLANDS B.V.	THE NETHERLANDS	1496	2020
COVID-19 mRNA Vaccine (nucleoside modified)	COMIRNATY concentrat pentru dispersie injectabila	concentrate for dispersion for injection	30 micrograms/ dose	BIONTECH MANUFACTURING GMBH	GERMANY	1528	2020
MenACWY Vaccine (Meningococcal group A, C, W and Y conjugate vaccine)	MENQUADFI	solution for injection		SANOFI PASTEUR	FRANCE	1483	2020