

ROMANIA

Newsletter

Year 25, No. 1 (97), 1st quarter of 2023

*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. 1522 of 9 October 2019 on approval of the Regulation for organisation and operation of the National Agency for Medicines and Medical Devices of Romania.

Order of the Minister of Health no. 857/2022 on approval of the Regulation for the organisation and operation of the National Agency for Medicines and Medical Devices of Romania;

Order of the Minister of Health no. 2318/2021 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania.

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

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

Law 95/2006 on healthcare reform, republished, as further amended and supplemented

Law 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented

Orders of the Minister of Health

Order of the Minister of Health no. 140/2023 on approval of the List of oral antibiotics and antipyretics whose distribution outside the territory of Romania is temporarily suspended for a period of 3 months

Order of the Minister of Health no. 80/2023 on approval of the structure and the Regulation for organisation and operation of the National Bioethics Committee for Medicinal Products and Medical Devices

Order of the Minister of Health no. 330/2023 on approval of the Methodological rules for clinical assessment and clinical investigations with medical devices and on repeal of Order of the Minister of Public Health no. 792/2006 on the conduct of the clinical investigation procedure and the performance assessment procedure for medical devices

Medicinal product batches recalled during the 1st quarter of 2023

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	Sargenor 1g/5ml	oral solution		arginine aspartate	Viatrix Healthcare Limited, Ireland	323181, 323182, 323291, 323467, 323608, 323773, 323754, 324095, 324096, 324098, 324266, 324265, 324267, 324811, 325112, 325204, 325291, 325446, 325600, 325707, 325706, 325802, 325930, 325929, 326032, 326037, 326036, 326099, 326100, 326376, 326377, 326583, 326584, 326736	recall from the market (warehouses and pharmacies), following discontinuation and avoiding overlap with the product registered as a supplement	Recall from the market at pharmacy level	21.03.2023
2	Regenon 25 mg	soft capsules	25 mg	Amfepranon e hydrochlori de	Temmler Pharma GmbH & Co. K, Germany		The European Commission's recall decision	Recall from the market at pharmacy level	25.01.2023

Applications for marketing authorisation/marketing authorisation renewal received during the 4th quarter of 2022

In the 4th quarter of 2022, 18 marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A10 - DRUGS USED IN DIABETES
A10 - DRUGS USED IN DIABETES
J05 – ANTIVIRAL DRUGS
J05 – ANTIVIRAL DRUGS
Homeopathic
B01A – ANTITHROMBOTIC AGENTS
N02B – OTHER ANALGESICS AND ANTIPYRETICS
J05A – DIRECT ACTING ANTIVIRAL DRUGS
J05A – DIRECT ACTING ANTIVIRAL DRUGS
J05A – DIRECT ACTING ANTIVIRAL DRUGS
J01D – OTHER BETA-LACTAM ANTIBACTERIALS
N05B – ANXIOLYTIC DRUGS
M01CC – PENICILLAMINE AND SIMILAR AGENTS
G02C – OTHER GYNECOLOGICALS
G04B – UROLOGICALS
V09G – CARDIOVASCULAR SYSTEM
J05A – DIRECT ACTING ANTIVIRAL DRUGS
J05A – DIRECT ACTING ANTIVIRAL DRUGS

Medicinal products authorised for marketing during the 4th quarter of 2022

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
1	ACETYLCYSTEINUM	ACC CU AROMA DE MURE 600 mg	oral powder, sachet	600mg	SANDOZ S.R.L.	ROMANIA	14 80 6	2022	01
2	ACICLOVIRUM	ACICLOVIR ROMPHARM 250 mg	powder for solution for infusion	250mg	ROMPHARM COMPANY S.R.L.	ROMANIA	14 77 5	2022	01
3	ACIDUM GADOTERICUM	CYCLOLUX 0.5 mmol/ml	solution for injection	0.5mmol/ml	SANOCHEMIA PHARMAZEUTIK A GMBH	AUSTRIA	14 80 7	2022	01
4	ACIDUM TIOCTICUM (ALFA-LIPOICUM)	ACID TIOCTIC ROMPHARM 600 mg/24 ml	solution for injection	600mg/24ml	ROMPHARM COMPANY S.R.L.	ROMANIA	14 82 9	2022	01
5	AMIODARONUM	AMIODARONA HAMELN 50 mg/ml	concentrate for solution for injection/infusion	50mg/ml	HAMELN PHARMA GMBH	GERMANY	14 77 6	2022	01
6	AMOXICILLINUM	AMOXICILINA ARENA 250 mg	capsules	250mg	ARENA GROUP SA	ROMANIA	14 82 2	2022	01
7	AMOXICILLINUM	AMOXICILINA ARENA 500 mg	capsules	500mg	ARENA GROUP SA	ROMANIA	14 82 3	2022	01
8	ANAGRELIDUM	GRENALVON 0.5 mg	capsules	0.5mg	LABORMED PHARMA S.A.	ROMANIA	14 81 5	2022	01
9	ANAGRELIDUM	GRENALVON 1 mg	capsules	1mg	LABORMED PHARMA S.A.	ROMANIA	14 81	2022	01

							6		
10	ANAGRELIDUM	ANAGRELIDA TEVA 0.5 mg	capsules	0.5mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	14 73 8	2022	01
11	APIXABANUM	APIXABAN TEVA 2.5 mg	film-coated tablets	2.5mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	14 79 6	2022	01
12	APIXABANUM	APIXABAN TEVA 5 mg	film-coated tablets	5mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	14 79 7	2022	01
13	ATRACURIUM	ATRACURIUM KALCEKS 10 mg/ml	solution for injection/infusion	10mg/ml	AS KALCEKS	LATVIA	14 70 0	2022	01
14	BENDAMUSTINUM	BENDAMUSTINA KABI 2.5 mg/ml	powder for concentrate for solution for infusion	2.5mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	14 75 6	2022	01
15	BETAXOLOLUM	BETAXOLOL MEDREG 20 mg	tablets	20mg	MEDREG S.R.O.	THE CZECH REPUBLIC	14 73 9	2022	01
16	BILASTINUM	BORENAR 2.5 mg/ml	oral solution	2.5 mg/ml	MENARINI INTERNATIONA L OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	14 74 5	2022	01
17	BILASTINUM	BORENAR 10 mg	orodispersible tablets	10mg	MENARINI INTERNATIONA L OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	14 74 4	2022	01

18	BISOPROLOLUM	CORSIB 2.5 mg	tablets	2.5mg	MEDREG S.R.O.	THE CZECH REPUBLIC	14 72 6	2022	01
19	BISOPROLOLUM	CORSIB 5 mg	tablets	5mg	MEDREG S.R.O.	THE CZECH REPUBLIC	14 72 7	2022	01
20	BISOPROLOLUM	CORSIB 10 mg	tablets	10mg	MEDREG S.R.O.	THE CZECH REPUBLIC	14 72 8	2022	01
21	BRIMONIDINUM	BRIMONIDINA ROMPHARM 2 mg/ml	eye drops, solution	2mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	14 82 8	2022	01
22	BUPIVACAINUM	BEMEVAX 5 mg/ml	solution for injection	5mg/ml	AS GRINDEKS.	LATVIA	14 80 8	2022	01
23	CABAZITAXELUM	CABAZITAXEL FRESENIUS KABI 20 mg/ml	concentrate for solution for infusion	20mg/ml	FRESENIUS KABI ROMANIA SRL	ROMANIA	14 74 9	2022	01
24	CASPOFUNGINUM	CASPOFUNGINA STADA M&D 50 mg	powder for concentrate for solution for infusion	50mg	STADA M&D SRL	ROMANIA	14 73 1	2022	01
25	CASPOFUNGINUM	CASPOFUNGINA STADA M&D 70 mg	powder for concentrate for solution for infusion	70mg	STADA M&D SRL	ROMANIA	14 73 2	2022	01
26	CITIZINUM	DEFUMOXAN 1.5 mg	tablets	1.5mg	AFLOFARM FARMACJA POLSKA SP. Z O.O.	POLAND	14 73 5	2022	01
27	CLOBETASOLUM	INFILEA 0.5 mg/g	cream	0.5mg/g	EGIS PHARMACEU- TICALS PLC.	HUNGARY	14 78 1	2022	01

28	CLOTRIMAZOLUM	CANESTEN GYN 3 200 mg	vaginal tablets	200mg	BAYER S.R.L.	ROMANIA	14 79 9	2022	01
29	COMBINATIONS	GATTART 680 mg/80 mg	chewable tablets	680mg/ 80mg	ALKALOID-INT D.O.O.	SLOVENIA	14 78 5	2022	01
30	COMBINATIONS	SEPTAZULEN PLUS MIERE SI LAMAIE 2 mg/0.6 mg/1.2 mg	tablets	2mg/0.6mg/ 1.2mg	PHARMA NET SOLUTIONS S.R.L.	ROMANIA	14 76 8	2022	01
31	COMBINATIONS	SEPTAZULEN PLUS PORTOCALE 2 mg/0.6 mg/1.2 mg	tablets	2mg/0.6mg/ 1.2mg	PHARMA NET SOLUTIONS S.R.L.	ROMANIA	14 76 9	2022	01
32	COMBINATIONS (ADAPALENUM+ BENZOYLIS PEROXIDUM)	EPIDUO FORTE 3 mg/25 mg/g	gel	3mg/25mg/g	GALDERMA INTERNATIONA L	FRANCE	14 79 5	2022	01
33	COMBINATIONS (BECLOMETASONUM+ FORMOTEROLUM)	VIVAIRE 100 micrograms/ 6 micrograms/dose	pressurised solution for inhalation	100micrograms/ 6micrograms/ dose	ZENTIVA, K.S.	THE CZECH REPUBLIC	14 70 7	2022	01
34	COMBINATIONS (CINARIZINUM+ DIMENHIDRINATUM)	VERTIGIX 20 mg/40 mg	tablets	20mg/40 mg	GALENICA S.A.	GREECE	14 74 7	2022	01
35	COMBINATIONS (DROSPIRENONUM+ ETINILESTRADIOLUM)	YASMIN 0.33 mg/3 mg	film-coated tablets	0.33mg/3mg	BAYER AG	GERMANY	14 80 1	2022	01
36	COMBINATIONS (ETONOGESTRELUM+ ETINILESTRADIOLUM)	TEYLA 0.120 mg/0.315 mg/ 24 de ore	vaginal delivery system	0.120mg/ 0.315mg/ 24 hours	HEATON K.S.	THE CZECH REPUBLIC	14 74 3	2022	01

37	COMBINATIONS (IBUPROFENUM+ PSEUDOEFEDRINUM)	USPAFEN SINUS 200 mg/30mg	coated tablets	200mg/30mg	US PHARMACIA SP. Z O.O.	POLAND	14 77 4	2022	01
38	COMBINATIONS (PARACETAMOLUM+ CAFEINUM)	SOLPADEINE EXTRACAFF 500 mg/65 mg	effervescent tablets	500mg/65mg	PERRIGO ROMANIA S.R.L.	ROMANIA	14 78 2	2022	01
39	COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	PERINDOPRIL/ INDAPAMIDA VIATRIS 2.5 mg/0.625 mg	film-coated tablets	2.5mg/ 0.625mg	VIATRIS LIMITED	IRELAND	14 76 4	2022	01
40	COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	PERINDOPRIL/ INDAPAMIDA VIATRIS 5mg/1.25 mg	film-coated tablets	5mg/1.25mg	VIATRIS LIMITED	IRELAND	14 76 5	2022	01
41	COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	VIACORLIX	film-coated tablets	7mg/2.5mg/ 5 mg	LES LABORATOIRES SERVIER	FRANCE	14 83 2	2022	01
42	COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	JANSITIN DUO 50 mg/850 mg	film-coated tablets	50mg/850mg	G.L. PHARMA GMBH	AUSTRIA	14 73 6	2022	01
43	COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	JANSITIN DUO 50 mg/1000 mg	film-coated tablets	50mg/1000 mg	G.L. PHARMA GMBH	AUSTRIA	14 73 7	2022	01
44	COMBINATIONS (SOLIFENACINUM SUCCINATE+ TAMSULOSINUM)	SOLIFENACIN/ TAMSULOZIN ADAMED 6 mg/0.4 mg	modified-release tablets	6mg/0.4mg	ADAMED PHARMA S.A.	POLAND	14 70 9	2022	01

45	COMBINATIONS (TRAMADOLUM+ DEXKETOPROFENUM)	SKUDEXA 75 mg/25 mg	granules for oral solution, sachet	75mg/25mg	MENARINI INTERNATIONA L OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	14 74 0	2022	01
46	DABIGATRANUM ETEXILATUM	TELEXER 110 mg	capsules	110mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	14 76 1	2022	01
47	DABIGATRANUM ETEXILATUM	TELEXER 150 mg	capsules	150mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	14 76 2	2022	01
48	DARUNAVIRUM	DARUNAVIR SANDOZ 400 mg	film-coated tablets	400mg	SANDOZ S.R.L.	ROMANIA	14 77 8	2022	01
49	DARUNAVIRUM	DARUNAVIR SANDOZ 600 mg	film-coated tablets	600mg	SANDOZ S.R.L.	ROMANIA	14 77 9	2022	01
50	DARUNAVIRUM	DARUNAVIR SANDOZ 800 mg	film-coated tablets	800mg	SANDOZ S.R.L.	ROMANIA	14 78 0	2022	01
51	DARUNAVIRUM	DARUNAVIR TEVA 800 mg	film-coated tablets	800mg	TEVA B.V.	HOLLAND	14 76 0	2022	01
52	DESFLURANUM	SUPRANE 100%	inhalation vapours, liquid	100%	BAXTER HEALTHCARE SRL	ROMANIA	14 82 6	2022	01
53	DEXKETOPROFENUM	XEDOFEN 50 mg/2 ml	solution for injection/infusion	50mg/2ml	AS KALCEKS	LATVIA	14 74 6	2022	01
54	DIMETHYL FUMARATE	DIMTRUZIC 120 mg	gastroresistant capsules	120mg	SANDOZ S.R.L.	ROMANIA	14 82 4	2022	01

55	DIMETHYL FUMARATE	DIMTRUZIC 240 mg	gastroresistant capsules	240mg	SANDOZ S.R.L.	ROMANIA	14 82 5	2022	01
56	DIOSMINUM	FLEBAZOL 500 mg	film-coated tablets	500mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14 72 4	2022	01
57	DIOSMINUM	FLEBAZOL 1000 mg	film-coated tablets	1000mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14 72 5	2022	01
58	DIVERSE-LACTOBACILLUS	SOFTIGYN min. 100.000.000 UFC	soft vaginal capsules		PROGE FARM S.R.L.	ITALY	14 82 0	2022	01
59	DIVERSE-LACTOBACILLUS	SOFTIGYN min. 100.000.000 UFC	vaginal capsules		PROGE FARM S.R.L.	ITALY	14 82 1	2022	01
60	DOBUTAMINUM	DOBUTAMINA HAMELN 5 mg/ml	solution for infusion	5mg/ml	HAMELN PHARMA GMBH	GERMANY	14 73 3	2022	01
61	DOBUTAMINUM	DOBUTAMINA HAMELN 12.5 mg/ml	concentrate for solution for infusion	12.5mg/ml	HAMELN PHARMA GMBH	GERMANY	14 73 4	2022	01
62	ENOXAPARINUM	CRUSIA 10000 UI (100 mg)/1.0 ml	solution for injection in pre-filled syringe	10000IU (100 mg)/1.0ml	LABORATORIOS FARMACEUTIC OS ROVI, S.A.	SPAIN	14 71 7	2022	01
63	ENOXAPARINUM	CRUSIA 8000 UI (80 mg)/0.8 ml	solution for injection in pre-filled syringe	8000IU(80 mg)/ 0.8ml	LABORATORIOS FARMACEUTIC OS ROVI, S.A.	SPAIN	14 71 6	2022	01
64	ENOXAPARINUM	CRUSIA 6000 UI (60 mg)/0.6 ml	solution for injection in pre-filled syringe	6000IU(60mg)/ 0.6ml	LABORATORIOS FARMACEUTICO S ROVI, S.A.	SPAIN	14 71 5	2022	01

65	ENOXAPARINUM	CRUSIA 4000 UI (40 mg)/0.4 ml	solution for injection in pre- filled syringe	4000IU(40 mg)/ 0.4ml	LABORATORIOS FARMACEUTIC OS ROVI, S.A.	SPAIN	14 71 4	2022	01
66	ENOXAPARINUM	CRUSIA 2000 UI (20 mg)/0.2 ml	solution for injection in pre- filled syringe	2000IU(20 mg)/ 0.2ml	LABORATORIOS FARMACEUTIC OS ROVI, S.A.	SPAIN	14 71 3	2022	01
67	ENOXAPARINUM	LOSMINA 2000 UI (20 mg)/0.2 ml	solution for injection in pre- filled syringe	2000IU(20mg) / 0.2ml	LABORATORIOS FARMACEUTIC OS ROVI, S.A.	SPAIN	14 71 8	2022	01
68	ENOXAPARINUM	LOSMINA 4000 UI (40 mg)/0.4 ml	solution for injection in pre- filled syringe	4000IU(40mg) / 0.4ml	LABORATORIOS FARMACEUTIC OS ROVI, S.A.	SPAIN	14 71 9	2022	01
69	ENOXAPARINUM	LOSMINA 6000 UI (60 mg)/0.6 ml	solution for injection in pre- filled syringe	6000IU(60mg)/ 0.6ml	LABORATORIOS FARMACEUTIC OS ROVI, S.A.	SPAIN	14 72 0	2022	01
70	ENOXAPARINUM	LOSMINA 8000 UI (80 mg)/0.8 ml	solution for injection in pre- filled syringe	8000IU(80mg)/ 0.8ml	LABORATORIOS FARMACEUTIC OS ROVI, S.A.	SPAIN	14 72 1	2022	01
71	ENOXAPARINUM	LOSMINA 10000 UI (100 mg)/1.0 ml	solution for injection in pre- filled syringe	10000IU(100mg) /1.0ml	LABORATORIOS FARMACEUTIC OS ROVI, S.A.	SPAIN	14 72 2	2022	01
72	ENTECAVIRUM	ENTECAVIR KRKA 0.5 mg	film-coated tablets	0.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14 75 8	2022	01
73	ENTECAVIRUM	ENTECAVIR KRKA 1 mg	film-coated tablets	1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14 75 9	2022	01
74	ERLOTINIBUM	ERLOTINIB ZENTIVA 100 mg	film-coated tablets	100mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14 69 8	2022	01

75	ERLOTINIBUM	ERLOTINIB ZENTIVA 150 mg	film-coated tablets	150mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14 69 9	2022	01
76	ERTAPENEMUM	ERTAPENEM APTAPHARMA 1 g	powder for concentrate for solution for infusion	1g	APTA MEDICA INTERNACIONA L D.O.O.	SLOVAKIA	14 75 5	2022	01
77	ETORICOXIBUM	GEROCOXAN 60 mg	film-coated tablets	60mg	G.L. PHARMA GMBH	AUSTRIA	14 79 1	2022	01
78	ETORICOXIBUM	GEROCOXAN 90 mg	film-coated tablets	90mg	G.L. PHARMA GMBH	AUSTRIA	14 79 2	2022	01
79	ETORICOXIBUM	GEROCOXAN 120 mg	film-coated tablets	120mg	G.L. PHARMA GMBH	AUSTRIA	14 79 3	2022	01
80	EVEROLIMUS	EVEROLIMUS ZENTIVA 2.5 mg	tablets	2.5 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14 80 9	2022	01
81	EVEROLIMUS	EVEROLIMUS ZENTIVA 5 mg	tablets	5 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14 81 0	2022	01
82	EVEROLIMUS	EVEROLIMUS ZENTIVA 10 mg	tablets	10 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	14 81 1	2022	01
83	EVEROLIMUS	VERIMMUS 5 mg	tablets	5mg	EGIS PHARMACEUTIC ALS PLC.	HUNGARY	14 83 0	2022	01
84	EVEROLIMUS	VERIMMUS 10 mg	tablets	10mg	EGIS PHARMACEUTIC ALS PLC.	HUNGARY	14 83 1	2022	01

85	EXTRACT ALERGENIC STANDARDIZAT DE POLEN DE AMBROZIE	RAGWIZAX 12 SQ-AMB	sublingual lyophilisate		ALK-ABELLO A/S	DENMARK	14 74 8	2022	01
86	EZETIMIBUM	EZOLETA 10 mg	tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14 75 3	2022	01
87	FULVESTRANTUM	FULVESTRANT ACCORD 250 mg	solution for injection in pre- filled syringe	250mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	14 79 4	2022	01
88	GLUCAGONUM *)	GLUCAGEN HYPOKIT 1 mg	powder and solvent for solution for injection	1mg	NOVO NORDISK FARMA SRL	ROMANIA	1	2022	01
89	HOMEOPATE	CORYZALIA	oral solution in single dose recipient		BOIRON	FRANCE	14 69 3	2022	01
90	HYDROCORTISONUM	SOFTACORT 3,35 mg/ml	eye drops, solution in single dose recipient	3.35mg/ml	LABORATOIRES THEA	FRANCE	14 72 3	2022	01
91	IBUPROFENUM	IBUPROFEN NUTRA ESSENTIAL OTC 100 mg	oral suspension, sachet	100mg	NUTRA ESSENTIAL OTC S.L.	SPAIN	14 81 7	2022	01
92	IBUPROFENUM	IBUPROFEN NUTRA ESSENTIAL OTC 200 mg	oral suspension, sachet	200mg	NUTRA ESSENTIAL OTC S.L.	SPAIN	14 81 8	2022	01
93	IBUPROFENUM	IBUPROFEN NUTRA ESSENTIAL OTC 400 mg	oral suspension, sachet	400mg	NUTRA ESSENTIAL OTC S.L.	SPAIN	14 81 9	2022	01

94	IBUPROFENUM	IBUPROFEN SKILLPHARMA 400 mg	granules for oral solution	400mg	SKILLPHARMA S.R.L.	ITALY	14 70 8	2022	01
95	IBUPROFENUM	IBUPROM COPII 40 mg/ml	oral suspension	40mg/ml	US PHARMACIA SP. Z O.O.	POLAND	14 81 3	2022	01
96	IMIPENEMUM + CILASTATINUM	IMIPENEM/CILASTATIN APTAPHARMA 500 mg/500 mg	powder for solution for infusion	500mg/500 mg	APTA MEDICA INTERNACIONA L D.O.O.	SLOVENIA	14 70 1	2022	01
97	HUMAN HEPATITIS B IMMUNOGLOBULIN)	ImmunoHBs 180IU/1mL	solution for injection	180IU/1ml	BESMAX PHARMA SOLUTIONS S.R.L.	ROMANIA	2	2022	01
98	HUMAN HEPATITIS B IMMUNOGLOBULIN)	ImmunoHBs 540IU/3mL	solution for injection	540IU/3ml	BESMAX PHARMA SOLUTIONS S.R.L.	ROMANIA	3	2022	01
99	HUMAN HEPATITIS B IMMUNOGLOBULIN)	ImmunoHBs 1000IU/3mL	solution for injection	1000IU/3ml	BESMAX PHARMA SOLUTIONS S.R.L.	ROMANIA	4	2022	01
100	INOSINUM	ISOPRINOSINA BILLEV 50 mg/ml	syrup	50mg/ml	BILLEV FARMACIJA VZHOD D.O.O.	SLOVENIA	14 74 1	2022	01
101	KALII IODIDUM	IODURA DE POTASIU SERB 65 mg	tablets	65mg	SERB S.A.	BELGIUM	14 78 3	2022	01
102	MESALAZINUM	AZZAVIX 500 mg	suppositories	500mg	FAES FARMA S.A.	SPAIN	14 70 2	2022	01
103	MICAFUNGINUM	MICAFUNGIN PHARMAZAC 50 mg	powder for concentrate for	50mg	PHARMAZAC S.A.	GREECE	14 69	2022	01

			solution for infusion				5		
104	MICAFUNGINUM	MICAFUNGIN PHARMAZAC 100 mg	powder for concentrate for solution for infusion	100mg	PHARMAZAC S.A.	GREECE	14 69 6	2022	01
105	MONTELUKASTUM	MONTELUKAST MEDREG 10 mg	film-coated tablets	10mg	MEDREG S.R.O.	THE CZECH REPUBLIC	14 75 4	2022	01
106	NORFLOXACINUM	NORFLOXACIN LAROPHARM 400 mg	film-coated tablets	400mg	LAROPHARM S.R.L.	ROMANIA	14 81 4	2022	01
107	OXIGENUM	OXIGEN LINDE 100% (v/v)	medicinal gas, compressed	100%(v/v)	LINDE GAZ ROMANIA S.R.L.	ROMANIA	14 79 8	2022	07
108	PARACETAMOLUM	PARACETAMOL ACCORD 1000 mg	effervescent tablets	1000mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	14 70 6	2022	01
109	PARACETAMOLUM	PARACETAMOL DR. MAX 500 mg	tablets	500mg	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	14 76 6	2022	01
110	PARACETAMOLUM	PARACETAMOL ACCORD 10 mg/ml	solution for infusion	10mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	14 82 7	2022	01
111	PEMETREXEDUM	PEMETREXED VIATRIS 25 mg/ml	concentrate for solution for infusion	25mg/ml	VIATRIS LIMITED	IRELAND	14 76 3	2022	01
112	RIFAXIMINUM	NORMIX 400 mg	film-coated tablets	400mg	ALFASIGMA S.P.A.	ITALY	14 69 4	2022	01
113	RIVAROXABANUM	RUNAPLAX 10 mg	film-coated tablets	10mg	SANDOZ S.R.L.	ROMANIA	14	2022	01

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114	RIVAROXABANUM	RUNAPLAX 15 mg	film-coated tablets	15mg	SANDOZ S.R.L.	ROMANIA	14 75 1	2022	01
115	RIVAROXABANUM	RUNAPLAX 20 mg	film-coated tablets	20mg	SANDOZ S.R.L.	ROMANIA	14 75 2	2022	01
116	RIVAROXABANUM	CLOSDERIVE 10 mg	film-coated tablets	10mg	SWYSSI AG	GERMANY	14 70 3	2022	01
117	RIVAROXABANUM	CLOSDERIVE 15 mg	film-coated tablets	15mg	SWYSSI AG	GERMANY	14 70 4	2022	01
118	RIVAROXABANUM	CLOSDERIVE 20 mg	film-coated tablets	20mg	SWYSSI AG	GERMANY	14 70 5	2022	01
119	RIVAROXABANUM	KARDATUXAN 2.5 mg	film-coated tablets	2.5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	14 77 0	2022	01
120	RIVAROXABANUM	KARDATUXAN 10 mg	film-coated tablets	10mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	14 77 1	2022	01
121	RIVAROXABANUM	KARDATUXAN 15 mg	film-coated tablets	15mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	14 77 2	2022	01
122	RIVAROXABANUM	KARDATUXAN 20 mg	film-coated tablets	20mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	14 77 3	2022	01
123	RIVAROXABANUM	RIVAROXABAN STADA 2.5 mg	film-coated tablets	2.5mg	STADA M&D S.R.L.	ROMANIA	14 78 6	2022	01

124	RIVAROXABANUM	RIVAROXABAN STADA 10 mg	film-coated tablets	10mg	STADA M&D S.R.L.	ROMANIA	14 78 7	2022	01
125	RIVAROXABANUM	RIVAROXABAN STADA 15 mg	film-coated tablets	15mg	STADA M&D S.R.L.	ROMANIA	14 78 8	2022	01
126	RIVAROXABANUM	RIVAROXABAN STADA 20 mg	film-coated tablets	20mg	STADA M&D S.R.L.	ROMANIA	14 78 9	2022	01
127	RIVAROXABANUM	RIVAROXABAN STADA 15 mg+20 mg	film-coated tablets	15mg+20mg	STADA M&D S.R.L.	ROMANIA	14 79 0	2022	01
128	SITAGLIPTINUM	JAZETA 25 mg/ml	oral solution	25mg/ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	14 69 7	2022	01
129	SITAGLIPTINUM	SUPROVIA 50 mg	film-coated tablets	50mg	MERCK ROMANIA SRL	ROMANIA	14 72 9	2022	01
130	SITAGLIPTINUM	SUPROVIA 100 mg	film-coated tablets	100mg	MERCK ROMANIA SRL	ROMANIA	14 73 0	2022	01
131	SITAGLIPTINUM	SITAGLIPTINA WORWAG 25 mg	film-coated tablets	25mg	WORWAG PHARMA GMBH & CO. KG.	GERMANY	14 80 3	2022	01
132	SITAGLIPTINUM	SITAGLIPTINA WORWAG 50 mg	film-coated tablets	50mg	WORWAG PHARMA GMBH & CO. KG.	GERMANY	14 80 4	2022	01
133	SITAGLIPTINUM	SITAGLIPTINA WORWAG 100 mg	film-coated tablets	100mg	WORWAG PHARMA GMBH & CO. KG.	GERMANY	14 80 5	2022	01
134	TERIFLUNOMIDUM	TEREBYO 14 mg	film-coated tablets	14mg	SANDOZ S.R.L.	ROMANIA	14 80	2022	01

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135	TERIFLUNOMIDUM	FEPLE 14 mg	film-coated tablets	14mg	ADALVO LIMITED	MALTA	14 80 2	2022	01
136	TERIFLUNOMIDUM	TERIFLUNOMIDA STADA 14 mg	film-coated tablets	14mg	STADA M&D SRL	ROMANIA	14 77 7	2022	01
137	TERIFLUNOMIDUM	BOZILOS 14 mg	film-coated tablets	14mg	EGIS PARMACEUTIC ALS PLC	HUNGARY	14 81 2	2022	01
138	TIANEPTINUM	LYXIT 12.5 mg	film-coated tablets	12.5 mg	ARENA GROUP S.A.	ROMANIA	14 74 2	2022	01
139	VARDENAFILUM	VIAVARDIS 10 mg	film-coated tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14 71 1	2022	01

EMA centrally authorised medicinal products notified for marketing in Romania during the 4th quarter of 2022

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
1	GALLIUM (68GA) GOZETOTIDA	LOCAMETZ 25 micrograms	Kit for radiopharmaceutical preparations	25 micrograms	NOVARTIS EUROPHARM LIMITED	ITALY	1692	2022	01
2	LUTETIUM (177LU) VIPIVOTIDA TETRAXETAN	PLUVICTO 1 000 MBq/ml	solution for injection/infusion	1000MBq/ml	NOVARTIS EUROPHARM LIMITED	IRELAND	1703	2022	01
3	MARALIXIBATUM	LIVMARLI 9.5 mg/ml	oral solution	9.5mg/ml	MIRUM PHARMACEUTICALS INTERNATIONAL B.V.	HOLLAND	1704	2022	01
4	MARIBAVIRUM	LIVTENCITY 200 mg	film-coated tablets	200mg	TAKEDA PHARM. INTERNATIONAL AG IRELAND BRANCH	IRELAND	1672	2022	01
5	NIRSEVIMABUM	BEYFORTUS 50 mg	solution for injection in pre-filled syringe	50mg	ASTRAZENECA AB	SWEDEN	1689	2022	01
6	NIRSEVIMABUM	BEYFORTUS 100 mg	solution for injection in pre-filled syringe	100mg	ASTRAZENECA AB	SWEDEN	1689	2022	01
7	RANIBIZUMABUM	XIMLUCI 10 mg/ml	solution for injection	10mg/ml	STADA ARZNEIMITTEL AG	GERMANY	1691	2022	01
8	SORAFENIBUM	SORAFENIB ACCORD 200 mg	film-coated tablets	200mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1696	2022	01

9	SPESOLIMABUM	SPEVIGO 450 mg	concentrate for solution for infusion	450mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	1688	2022	01
10	TERIFLUNOMIDUM	TERIFLUNOMIDA MYLAN 14 mg	film-coated tablets	14mg	MYLAN PHARMACEUTICALS LIMITED	IRELAND	1698	2022	01
11	TERIPARATIDUM	TERIPARATIDE SUN 20 micrograms/ 80 microlitri	solution for injection in pre-filled pen	20micrograms /80microliters	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	1697	2022	01