

ROMANIA

Newsletter

Year 26, No. 1 (101), 1st quarter of 2024

*National Agency
for Medicines and Medical Devices
of Romania*

All data herein represent official information and are under direct authority of the National Agency for Medicines and Medical Devices of Romania.

The entire content of the present publication lies under complete legislative protection of the National Agency for Medicines and Medical Devices of Romania.

Any use of present publication content for revenue purposes or its marketing without express consent of the National Agency for Medicines and Medical Devices of Romania is forbidden and punishable by law.

The National Agency for Medicines and Medical Devices of Romania reserves exclusive publishing rights.

ISSN 1583-347X

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, as further amended and supplemented;

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) 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)**

TABLE OF CONTENTS

Government decisions

Government Decision no. 1004/2023 on approval of the 2023-2030 National Health Strategy

Government Decision no. 1006/2023 on approval of the 2023-2030 National Vaccination Strategy in Romania

Orders

Order of the Minister of Health no. 1274/2024 on approval of the the national medical practice protocol for the treatment of the infection with the SARS-CoV-2 virus

Medicinal product batches recalled during the 1st quarter of 2024

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	ACC JUNIOR 20 mg/ml	syrup	20 mg/ml	acetilcisteinum	Hexal AG, Germany	MS7986, ND6093	The presence of small, black particles detected in the solution	Voluntary recall from the market	29.03.2024
2	Lescol XL 80 mg	prolonged-release tablets	80 mg	fluvastatin (as fluvastatin sodium)	Novartis Pharma GmbH, Germany	FJ5061, GC4079	Termination of MA validity in Romania	Voluntary recall from the market	20.03.2024
3	Vitamina C Arena 750 mg solution for injection	solution for injection	750 mg	acidum ascorbicum	Arena Group S.A., Romania	A22N1L	Out-of-specification results for the following parameters: Aspect, Absorbance of the solution at 420nm, Extractable volume, Chemically related substances	Recall upon NAMMDR request	29.02.2024
4	Corsib 2.5 mg	tablets	2.5 mg	bisoprololum	Gemax Pharma s.r.o. the Czech Republic	P8033A	Out-of-specification results	Voluntary recall from the market	06.02.2024

Applications for marketing authorisation/marketing authorisation renewal received during the 4th quarter of 2023

In the 4th quarter of 2023, 36 marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

AUTHORISATION	RENEWAL
J02 – Antiinfectives for systemic use	J01 – Antibacterial drugs
A02B – Drugs for peptic ulcer and gastro-oesophageal reflux disease	J01 – Antibacterial drugs
J01 – Antibacterial drugs	N02 – Analgesic drugs
R01 – Nasal preparations	N06 – Psychoanaleptics
M02 – Topical products for joint and muscular pain	N06 – Psychoanaleptics
M01 – Anti-inflammatory and antirheumatic drugs	R01 – Nasal preparations
N02 – Analgesic drugs	A11 – Vitamins
N02 – Analgesic drugs	B01 – Antithrombotic agents
N02 – Analgesic drugs	A12 – Mineral supplements
M01 – Anti-inflammatory and antirheumatic drugs	G03 – Sex hormones and modulators of the genital system
N03 – Antiepileptic drugs	N06 – Psychoanaleptics
N03 – Antiepileptic drugs	N06 – Psychoanaleptics
N03 – Antiepileptic drugs	
J05 – Antiviral drugs	
J01 – Antibacterial drugs	
A06 – Drugs for constipation	
N02 – Analgesic drugs	
R06 – Antihistamines for systemic use	
C05 – Vasoprotective drugs	
N05 – Psycholeptics drugs	
XRNIT – Homeopathic medicinal products	
B01 – Antithrombotic agents	
B01 – Antithrombotic agents	
N02 – Analgesic drugs	

Medicinal products authorised for marketing during the 4th quarter of 2023

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	ABIRATERONUM	ABIRATERONA POLISANO 250 mg	film-coated tablets	250mg	POLISANO PHARMACEUTICALS S.A.	ROMANIA	15181	2023
2	ABIRATERONUM	ABIRATERONA POLISANO 500 mg	film-coated tablets	500mg	POLISANO PHARMACEUTICALS S.A.	ROMANIA	15182	2023
3	ACETYLCYSTEINUM	MUCOFORTIN 600 mg	effervescent tablets	600mg	NATUR PRODUKT ZDROVIT SP. Z O.O.	POLAND	15160	2023
4	ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC ACCORD 4 mg/100 ml	solution for infusion	4mg/100ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15183	2023
5	ALLOPURINOLUM	ALOPURINOL GEMAX PHARMA 300 mg	tablets	300mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15195	2023
6	AMPICILLINUM + SULBACTAM	AMPIPLUS 2000 mg/1000 mg	powder for solvent for injection/infusion	2000mg/ 1000mg	ANTIBIOTICE S.A.	ROMANIA	15175	2023
7	ANIDULAFUNGINUM	ANIDULAFUNGINA ROMPHARM 100 mg	concentrate for solution for infusion	100mg	ROMPHARM COMPANY S.R.L.	ROMANIA	15237	2023

8	BENZYDAMINUM	FARINGOSEPT 1.5 mg/ml	oromucosal spray, solution	1.5mg/ml	TERAPIA S.A.	ROMANIA	15222	2023
9	BENZYDAMINUM	FARINGOSEPT 3 mg/ml	oromucosal spray, solution	3mg/ml	TERAPIA S.A.	ROMANIA	15223	2023
10	BENZYDAMINUM	ZOTRINA 1.5 mg/ml	oromucosal spray, solution	1.5mg/ml	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15253	2023
11	BETAHISTINUM	ACCORD, BETAHISTINE DICHLORHYDRATE, 24 mg	tablets	24 mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15161	2023
12	CALCII CHLORIDUM	CALRECIA 100 mmol/l	solution for infusion	100mmol/l	FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH	GERMANY	15168	2023
13	CEFIXIMUM	CEFIXIMA STADA 200 mg	film-coated tablets	200mg	STADA M&D SRL	ROMANIA	15171	2023
14	CEFIXIMUM	CEFIXIMA STADA 400 mg	film-coated tablets	400mg	STADA M&D SRL	ROMANIA	15172	2023
15	CETIRIZINUM	CETIRIZINE PXGPHARMA 10 mg	film-coated tablets	10mg	PXG PHARMA GMBH	GERMANY	15249	2023
16	CLOBETASOLUM	INFILEA 500 µg/ml	shampoo	50µg/ml	EGIS PHARMACEUTICA LS PLC.	HUNGARY	15228	2023

17	COMBINATIONS	GNAK 50 mg/ml	solution for infusion	50mg/ml	BAXTER HEALTHCARE SRL	ROMANIA	15196	2023
18	COMBINATIONS	OLIMEL N12E	emulsion for infusion		BAXTER HEALTHCARE S.R.L.	ROMANIA	15197	2023
19	COMBINATIONS (ACIDUM ACETYLSALICYLICUM+ ACIDUM ASCORBICUM)	ASPIRIN PLUS C FORTE 800 mg/480 mg	effervescent tablets	800mg/480mg	BAYER S.R.L.	ROMANIA	15180	2023
20	COMBINATIONS (ADAPALENUM+ BENZOYLIS PEROXIDUM)	EPIDUO FORTE 3 mg/25 mg/g	gel	3mg/25mg/g	GALDERMA INTERNATIONAL	FRANCE	15207	2023
21	COMBINATIONS (ARTICAINUM+ ADRENALINUM)	NORMOCAIN 40 mg/0.005 mg/ml	solution for injection	40mg/0.005mg/ml	LABORATORIOS NORMON S.A.	SPAIN	15165	2023
22	COMBINATIONS (ARTICAINUM+ ADRENALINUM)	NORMOCAIN 40 mg/0.010 mg/ml	solution for injection	40mg/0.01mg/ml	LABORATORIOS NORMON S.A.	SPAIN	15166	2023
23	COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	LIRTONEN 5 mg/10 mg	film-coated tablets	10mg/5mg	ALKALOID-INT D.O.O.	SLOVENIA	15213	2023
24	COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	LIRTONEN 5 mg/10 mg	film-coated tablets	10mg/10mg	ALKALOID-INT D.O.O.	SLOVENIA	15214	2023
25	COMBINATIONS (ESTRADIOLUM+ DIDROGESTERONUM)	FEMOSTON 2/10	film-coated tablets		VIATRIS HEALTHCARE LIMITED	IRELAND	15178	2023

26	COMBINATIONS (FERROSI GLUCONAS+ ACIDUM FOLICUM)	TOTYLEM 60 mg/0.4 mg	film-coated tablets	60mg/ 0.4mg	LABORATOIRE INNOTECH INTERNATIONAL	FRANCE	15167	2023
27	COMBINATIONS (IBUPROFENUM+ PSEUDOEPHEDRINUM)	BIOFEN RACEALA SI GRIPA 200 mg/30 mg	film-coated tablets	200mg/ 30mg	BIOFARM S.A.	ROMANIA	15192	2023
28	COMBINATIONS (LEVODOPUM+ BENSERAZIDUM)	MADOPAR DEPOT	Modified-release capsules	100mg+ 25mg	ROCHE ROMANIA S.R.L.	ROMANIA	7	2023
29	COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LECIGON 20 mg/5 mg/20 mg/ml	intestinal gel	20mg/5mg /20mg/ml	LOBSOR PHARMACEUTICALS AB	SWEDEN	15254	2023
30	COMBINATIONS (NATRII ALGINAS+NATRII HYDROGENOCARBONAS +CALCII CARBONAS)	GAVISCON FORTE CU AROMA DE ZMEURA	chewable tablets	250mg/ 106.5mg/ 187.5mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	15244	2023
31	COMBINATIONS (NATRII ALGINAS+NATRII HYDROGENOCARBONAS +CALCII CARBONAS)	GAVISCON FORTE CU AROMA DE FRUCTE DE PADURE	chewable tablets	250mg/ 106.5mg/ 187.5mg	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	15245	2023
32	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA ACCORD 20 mg/5 mg	film-coated tablets	20mg/5mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	15162	2023

33	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA ACCORD 40 mg/5 mg	film-coated tablets	40mg/5mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	15163	2023
34	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA ACCORD 40 mg/10 mg	film-coated tablets	40mg/ 10mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	15164	2023
35	COMBINATIONS (PARACETAMOLUM+ ACIDUM ASCORBICUM+ CHLORPHENAMINUM)	BIOFLU HOT DRINK 500 mg/200 mg/4 mg	chewable tablets	500mg/ 200mg/ 4mg	BIOFARM S.A.	ROMANIA	15173	2023
36	COMBINATIONS (PARACETAMOLUM+ ACIDUM ASCORBICUM+ CHLORPHENAMINUM)	BIOFLU HOT DRINK MAX 1000 mg/200 mg/4 mg	granules for oral suspension, sachet	1000mg/ 200mg/ 4mg	BIOFARM S.A.	ROMANIA	15174	2023
37	COMBINATIONS (PARACETAMOLUM+ IBUPROFENUM)	CAFFETIN DUO 500 mg/200 mg	tablets	500mg/ 200mg	ALKALOID-INT D.O.O.	SLOVENIA	15203	2023
38	COMBINATIONS (PARACETAMOLUM+ PSEUDOEPHEDRINUM)	BIOFLU SINUS 500 mg/30 mg	film-coated tablets	500mg/ 30mg	BIOFARM S.A.	ROMANIA	15194	2023
39	CYTARABINUM	CITARABINA ACCORD 20 mg/ml	solution for injection/infusion	20mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15259	2023

40	DABIGATRANUM ETEXILATUM	GRIBERO 75 mg	capsules	75mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15204	2023
41	DABIGATRANUM ETEXILATUM	GRIBERO 110 mg	capsules	110mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15205	2023
42	DABIGATRANUM ETEXILATUM	GRIBERO 150 mg	capsules	150mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15206	2023
43	DABIGATRANUM ETEXILATUM	DAXANLO 75 mg	capsules	75mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15250	2023
44	DABIGATRANUM ETEXILATUM	DAXANLO 110 mg	capsules	110mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15251	2023
45	DABIGATRANUM ETEXILATUM	DAXANLO 150 mg	capsules	150mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15252	2023
46	DAPAGLIFLOZINUM	DAGRAFORS 5 mg	film-coated tablets	5mg	KRKA, D.D. NOVO MESTO	SLOVENIA	15184	2023
47	DAPAGLIFLOZINUM	DAGRAFORS 10 mg	film-coated tablets	10mg	KRKA, D.D. NOVO MESTO	SLOVENIA	15185	2023
48	DIOSMINUM	FLAXIOS FORTE 1000 mg	film-coated tablets	1000mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15235	2023
49	ENZALUTAMIDUM	ENZALUTAMIDA SANDOZ 40 mg	film-coated tablets	40mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15209	2023
50	ENZALUTAMIDUM	ENZALUTAMIDA SANDOZ 80 mg	film-coated tablets	80mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15210	2023
51	ERLOTINIBUM	FOKLEROS 100 mg	film-coated tablets	100mg	ALKALOID-INT D.O.O.	SLOVENIA	15219	2023

52	ERLOTINIBUM	FOKLEROS 150 mg	film-coated tablets	150mg	ALKALOID-INT D.O.O.	SLOVENIA	15220	2023
53	ERTAPENEMUM	ERTAPENEM ACS DOBFAR 1 g	powder for concentrate for solution for infusion	1g	ACS DOBFAR S.P.A	ITALY	15225	2023
54	ESCITALOPRAMUM	ESCITALOPRAM GRINDEKS 5 mg	film-coated tablets	5mg	AS GRINDEKS	LATVIA	15154	2023
55	ESCITALOPRAMUM	ESCITALOPRAM GRINDEKS 10 mg	film-coated tablets	10mg	AS GRINDEKS	LATVIA	15155	2023
56	ESCITALOPRAMUM	ESCITALOPRAM GRINDEKS 20 mg	film-coated tablets	20mg	AS GRINDEKS	LATVIA	15156	2023
57	ESCITALOPRAMUM	ESCITALOPRAM GEMAX PHARMA 10 mg	film-coated tablets	10mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15246	2023
58	EVEROLIMUS	EVEROLIMUS ACCORD 2.5 mg	tablets	2.5mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15188	2023
59	EVEROLIMUS	EVEROLIMUS ACCORD 5 mg	tablets	5mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15189	2023
60	EVEROLIMUS	EVEROLIMUS ACCORD 10 mg	tablets	10mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15190	2023
61	FEBUXOSTATUM	FORURE 80 mg	film-coated tablets	80mg	EGIS PHARMACEUTICAL PLC	HUNGARY	15201	2023

62	FEBUXOSTATUM	FORURE 120 mg	film-coated tablets	120mg	EGIS PHARMACEUTICAL PLC	HUNGARY	15202	2023
63	FLECAINIDUM	AMARHYTON 50 mg	prolonged-release capsules	50mg	SWYSSI AG	GERMANY	15257	2023
64	FLECAINIDUM	AMARHYTON 100 mg	prolonged-release capsules	100mg	SWYSSI AG	GERMANY	15258	2023
65	FLUDARABINUM	FLUDARABINA ACCORD 25 mg/ml	concentrate for solution for injection/infusion	25mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15126	2023
66	FLURBIPROFENUM	STREPSILS INTENSIV CIRESE SI MENTA 8.75 mg/dose	oromucosal spray, solution	8.75mg/dose	RECKITT BENCKISER (ROMANIA) S.R.L.	ROMANIA	15229	2023
67	FLURBIPROFENUM	VOCAFEN PORTOCALE 8.75 mg	tablets	8.75mg	STADA ARZNEIMITTEL AG	GERMANY	15224	2023
68	FUROSEMIDUM	FUROSEMID BASI 10 mg/ml	solution for injection/infusion	10mg/ml	LABORATORIOS BASI-INDUSTRIA FARMACEUTICA S.A.	PORTUGAL	15153	2023
69	HYDROCORTISONUM	HIDROCORTIZON PANPHARMA 100 mg	powder and solvent for solution for injection/infusion	100mg	PANPHARMA	FRANCE	15256	2023
70	IBUPROFENUM	BIOFEN 50 mg/g	gel	50mg/g	BIOFARM S.A.	ROMANIA	15191	2023
71	IBUPROFENUM	BIOFEN PENTRU COPII 100 mg/5 ml	oral suspension	100mg/5ml	BIOFARM S.A.	ROMANIA	15193	2023

72	LEVOFLOXACINUM	TAVOFLOX 250 mg	film-coated tablets	250mg	TERAPIA S.A.	ROMANIA	15226	2023
73	LEVOFLOXACINUM	TAVOFLOX 500 mg	film-coated tablets	500mg	TERAPIA S.A.	ROMANIA	15227	2023
74	LINEZOLIDUM	LINEZOLID KABI 2 mg/ml	solution for infusion	2mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	15234	2023
75	LORATADINUM	ALERITYN 10 mg	tablets	10mg	BIOFARM S.A.	ROMANIA	15261	2023
76	MIGLUSTATUM	MIGLUSTAT ACCORD 100 mg	capsules	100mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15170	2023
77	OMEPRAZOLUM	OMECOD 10 mg	gastroresistant capsules	10mg	TERAPIA S.A.	ROMANIA	15239	2023
78	OMEPRAZOLUM	OMECOD 20 mg	gastroresistant capsules	20mg	TERAPIA S.A.	ROMANIA	15240	2023
79	OMEPRAZOLUM	OMECOD 40 mg	gastroresistant capsules	40mg	TERAPIA S.A.	ROMANIA	15241	2023
80	OPIUM	DROPIZOL 10 mg/ml	oral drops, solution	10mg/ml	PHARMANOVIA A/S	DENMARK	15179	2023
81	PANCREATINUM	KREON 20000	gastroresistant capsules	300mg	VIATRIS HEALTHCARE LIMITED	IRELAND	15186	2023
82	PANCREATINUM	PANKREAL 35000	gastroresistant capsules	420mg	VIATRIS HEALTHCARE LIMITED	IRELAND	15187	2023
83	PARACETAMOLUM	PARACETAMOL PXGPHARMA 500 mg	film-coated tablets	500mg	PXG PHARMA GMBH	GERMANY	15248	2023

84	PLANTS (PELARGONIUM ROOT EXTRACT)	PELAFEN MED 20 mg/2.5 ml	syrup	20mg/ 2.5ml	PHYTOPHARM KLEKA S.A.	POLAND	15238	2023
85	PLANTS (THYME+ IVY EXTRACT)	BRONCHIPRET EXPECTORANT	syrup		BIONORICA SE	GERMANY	15211	2023
86	PLANTS (THYME+ IVY EXTRACT)	BRONCHIPRET CIMBRU SI IEDERA	syrup		BIONORICA SE	GERMANY	15212	2023
87	POSACONAZOLUM	POSACONAZOL MSN LABORATORIES 300 mg	concentrate for solution for infusion	300mg	VIVANTA GENERICS S.R.O.	THE CZECH REPUBLIC	15208	2023
88	PROGESTERONUM	PROLUTEX 25 mg	solution for injection in pre- filled syringe	25mg	IBSA FARMACEUTICI ITALY SRL	ITALY	15198	2023
89	RIVAROXABANUM	XABOPLAX 2.5 mg	film-coated tablets	2.5mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15230	2023
90	RIVAROXABANUM	XABOPLAX 10 mg	film-coated tablets	10mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15231	2023
91	RIVAROXABANUM	XABOPLAX 15 mg	film-coated tablets	15mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15232	2023
92	RIVAROXABANUM	XABOPLAX 20 mg	film-coated tablets	20mg	SANDOZ PHARMACEUTICALS S.R.L.	ROMANIA	15233	2023
93	SILODOSINUM	SIDARSO 4 mg	capsules	4mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15199	2023

94	SILODOSINUM	SIDARSO 8 mg	capsules	8mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15200	2023
95	SITAGLIPTINUM	SITAGLIPTINA HELCOR 50 mg	film-coated tablets	50mg	AC HELCOR PHARMA S.R.L.	ROMANIA	15176	2023
96	SITAGLIPTINUM	SITAGLIPTINA HELCOR 100 mg	film-coated tablets	100mg	AC HELCOR PHARMA S.R.L.	ROMANIA	15177	2023
97	SOLIFENACINUM SUCCINATE	SOLIFENACIN MSN LABORATORIES 5 mg	film-coated tablets	5mg	VIVANTA GENERICS S.R.O.	THE CZECH REPUBLIC	15217	2023
98	SOLIFENACINUM SUCCINATE	SOLIFENACIN MSN LABORATORIES 10 mg	film-coated tablets	10mg	VIVANTA GENERICS S.R.O.	THE CZECH REPUBLIC	15218	2023
99	SUGAMMADEXUM	SUGAMMADEX KALCEKS 100 mg/ml	solution for injection	100mg/ml	AS KALCEKS	LATVIA	15157	2023
100	SUGAMMADEXUM	SUGAMMADEX APTAPARMA 100 mg/ml	solution for injection	100mg/ml	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	15158	2023
101	SUGAMMADEXUM	SUGAMMADEX BAXTER 100 mg/ml	solution for injection	100mg/ml	BAXTER HOLDING BV	THE NETHERLANDS	15159	2023
102	SUGAMMADEXUM	SUGAMMADEX AGUETTANT 10 mg/ml	solution for injection in pre-filled syringe	10mg/ml	LABORATOIRE AGUETTANT	FRANCE	15242	2023
103	SUGAMMADEXUM	SUGAMMADEX AGUETTANT 50 mg/ml	solution for injection in pre-filled syringe	50mg/ml	LABORATOIRE AGUETTANT	FRANCE	15243	2023
104	T AFLUPROSTUM	SAFLUTAN 15 micrograms/ml	eye drops, solution	15micro-grams/ml	SANTEN OY	FINLAND	15215	2023

105	TREOSULFANUM	TREOSULFAN TILLOMED 5 g	powder for solution for infusion	5g	LABORATORIOS TILLOMED SPAIN S.L.	SPAIN	15221	2023
106	TROXERUTINUM	DEVARICID 20 mg/g	gel	20mg/g	BIOFARM S.A.	ROMANIA	15260	2023
107	ULIPRISTALUM ACETATUM	FEMKE 30 mg	film-coated tablets	30mg	VIATRIS LIMITED	IRELAND	15169	2023
108	VERDE DE INDOCIANINA	VERDYE 5 mg/ml	powder for solution for injection	5mg/ml	DIAGNOSTIC GREEN LIMITED	IRELAND	15255	2023
109	VORICONAZOLUM	VORICONAZOL HAMELN 200 mg	powder for solution for infusion	200mg	HAMELN PHARMA GMBH	GERMANY	15236	2023

EMA centrally authorised medicinal products notified for marketing in Romania during the 4th quarter of 2023

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	DABRAFENIBUM	FINLEE 10 mg	dispersible tablets	10mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1767	2023
2	ELRANATAMABUM	ELREXFIO 40 g/ml	solution for injection	40mg/ml	PFIZER EUROPE MA EEIG	THE NETHERLANDS	1770	2023
3	PIRTOBRUTINIBUM	JAYPIRCA 50 mg	film-coated tablets	50mg	ELI LILLY NEDERLAND B.V.	THE NETHERLANDS	1738	2023
4	PIRTOBRUTINIBUM	JAYPIRCA 100 mg	film-coated tablets	100mg	ELI LILLY NEDERLAND B.V.	THE NETHERLANDS	1738	2023
5	ZILUCOPLANUM	ZILBRYSQ 16.6 mg	solution for injection in pre-filled syringe	16.6mg	UCB PHARMA GMBH	THE NETHERLANDS	1764	2023
6	ZILUCOPLANUM	ZILBRYSQ 23 mg	solution for injection in pre-filled syringe	23mg	UCB PHARMA GMBH	THE NETHERLANDS	1764	2023
7	ZILUCOPLANUM	ZILBRYSQ 32.4 mg	solution for injection in pre-filled syringe	32.4mg	UCB PHARMA GMBH	THE NETHERLANDS	1764	2023