

*ROMANIA*

*Newsletter*

**Year 26, No. 3 (103), 3<sup>rd</sup> quarter of 2024**

*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, 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**

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### **Orders**

Order of the Minister of Health no. 3994 of 2024 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania

Order of the Minister of Health no. 1474 of 5 August 2021 on set up and operation of the group of experts responsible for technical standpoints on documents under EU debate, also ensuring representation in meetings of EU working entities

Order of the Minister of Health no. 368/2017 on approval of the Rules for the calculation method and the procedure for approving the maximum prices of medicinal products for human use, as further amended and supplemented

### **Regulations**

Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices

## Medicinal product batches recalled during the 3<sup>rd</sup> quarter of 2024

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH/parallel import authorisation holder	Batch	Grounds for recall	Proposed action	Date of recall
1	Pantoprazol SUN 40mg powder for solution for injection,	powder for solution for injection	40 mg	Pantoprazolum	Sun Pharmaceutical Industries Europe B.V.,the Netherlands	HAE2976A/expiry date 11.2025	Out-of-specification results	Voluntary recall	24.07.2024
2	ATOMOXETINA ACCORD 10 mg capsules	capsules	10 mg	Atomoxetine	Accord Healthcare Polska Sp. z o.o., Poland,		Out-of-specification results	Voluntary recall	19.07.2024
3	ATOMOXETINA ACCORD 18 mg capsules	capsules	18 mg	Atomoxetine	Accord Healthcare Polska Sp. z o.o., Poland,		Out-of-specification results	Voluntary recall	19.07.2024
4	ATOMOXETINA ACCORD 25 mg capsules	capsules	25 mg	Atomoxetine	Accord Healthcare Polska Sp. z o.o., Poland,		Out-of-specification results	Voluntary recall	19.07.2024
5	ATOMOXETINA ACCORD 40 mg capsules	capsules	40 mg	Atomoxetine	Accord Healthcare Polska Sp. z o.o., Poland,		Out-of-specification results	Voluntary recall	19.07.2024
6	ATOMOXETINA ACCORD 60 mg capsules	capsules	60 mg	Atomoxetine	Accord Healthcare Polska Sp. z o.o., Poland,		Out-of-specification results	Voluntary recall	19.07.2024
7	ATOMOXETINA ACCORD 80 mg capsules	capsules	80 mg	Atomoxetine	Accord Healthcare Polska Sp. z o.o., Poland,		Out-of-specification results	Voluntary recall	19.07.2024
8	ATOMOXETINA ACCORD 100 mg capsules	capsules	100 mg	Atomoxetine	Accord Healthcare Polska Sp. z o.o., Poland,		Out-of-specification results	Voluntary recall	19.07.2024

9	BITINEX 10 mg capsules	capsules	10 mg	Atomoxetine	Egis Pharmaceuticals PLC, Hungary	12050113/expiry date 11.2024	Out-of- specification results	Voluntary recall	23.08.2024
10	ATOFAB 10 mg capsules	capsules	10 mg	Atomoxetine	Lannacher Heilmittel Ges.m.b.H., Austria	E01570/expiry date 09.2024 E05931/expiry date 10.2025	Out-of- specification results	Voluntary recall	26.07.2024
11	ATOFAB 40 mg capsules	capsules	40 mg	Atomoxetine	Lannacher Heilmittel Ges.m.b.H., Austria	E01584/expiry date 09.2024	Out-of- specification results	Voluntary recall	26.07.2024
12	CONTROLGAST DUO 680/80mg chewable tablets	chewable tablets	680mg/80mg	Calcium Carbonate/Magnesium Carbonate	S.C. BIO EEL S.R.L.		date of expiry of the marketing authorisation	Voluntary recall	23.08.2024
13	FARINGO HOT DRINK 500 mg/200 mg/ 4 mg granules for oral solution	granules for oral solution	500 mg/200 mg/ 4 mg	Paracetamol+ Acidum Ascorbicum+ Chlorphenaminum	Terapia SA , Romania	221572/expiry date 10.2024	Out-of- specification results	Recall upon NAMMDR request	01.08.2024
14	LOPERAMID DR.MAX 2 mg capsules	capsules	2 mg	Loperamidum	Dr.Max Pharma s.r.o., the Czech Republic		European Commission Decision (2024)3294 final 24.05.2024	Recall upon NAMMDR request	08.07.2024
15	Apixaban Teva 2.5 mg film- coated tablets	film-coated tablets	2.5 mg	Apixabanum	Teva Phamaceuticals S.R.L., Romania		product recalled from distributor level following a legal conflict	Voluntary recall	04.04.2024
16	Apixaban Teva 5 mg film-coated tablets	film-coated tablets	5 mg	Apixabanum	Teva Phamaceuticals S.R.L., Romania		product recalled from distributor level following a legal conflict	Voluntary recall	04.04.2024

## Applications for marketing authorisation/marketing authorisation renewal received during the 2<sup>nd</sup> quarter of 2024

28 marketing authorisation/marketing authorisation renewal applications for medicinal products have been received during the 2<sup>nd</sup> quarter of 2024, corresponding to the following therapeutic groups:

AUTHORISATION	RENEWAL
J07A – Bacterial Vaccines	N02 – Analgesics
M02 –Topical products for joint and muscular pain	R01 – Nasal preparations
G04 – Urologicals	D01 – Antifungals for dermatological use
C03 – Diuretics	J04 – Antimycobacterials
M02 –Topical products for joint and muscular pain	C04 – Peripheral vasodilators
B01 – Antithrombotic Agents	M01 – Antiinflammatory and antirheumatic products
B01 – Antithrombotic Agents	D07 – Corticosteroids, dermatologicals preparations
M01 – Antiinflammatory and antirheumatic products	L04 – Immunosuppressants
N02 – Analgesics	L04 – Immunosuppressants
N02 – Analgesics	L04 – Immunosuppressants
A02 – Drugs for acid related disorders	N07 – Other nervous system drugs
A05 – Bile and liver therapy	J05 – Antivirals for systemic use
N01 - Anesthetics	
C07 – Beta Blocking Agents	
C07 – Beta Blocking Agents	
C07 – Beta Blocking Agents	



## Medicinal products authorised for marketing during the 2<sup>nd</sup> quarter of 2024

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	ABACAVIRUM	ABACAVIR AUROBINDO 300 mg	film-coated tablets	300mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	15483	2024
2	ACICLOVIRUM	ZIRVIN 200 mg	tablets	200mg	ZENTIVA K.S.	THE CZECH REPUBLIC	15468	2024
3	ACICLOVIRUM	ZIRVIN 400 mg	tablets	400mg	ZENTIVA K.S.	THE CZECH REPUBLIC	15469	2024
4	ALFACALCIDOLUM	ALFACALCIDOL HEATON 0.50 micrograms	soft capsules	0.50 micrograms	HEATON K.S.	THE CZECH REPUBLIC	15417	2024
5	ALFACALCIDOLUM	ALFACALCIDOL TERAPIA 0.5 micrograms	soft capsules	0.5mg	TERAPIA S.A.	ROMANIA	15489	2024
6	ANAGRELIDUM	ANAGRELIDA ACCORD 0.5 mg	capsules	0.5mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	15510	2024
7	ANAGRELIDUM	ANAGRELIDA ACCORD 1 mg	capsules	1mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	15511	2024
8	ANIDULAFUNGINUM	ANIDULAFUNGINA ACCORD 100 mg	powder for concentrate for solution for infusion	100mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15509	2024

9	ATORVASTATINUM	ATORVASTATINA GEMAX PHARMA 10 mg	film-coated tablets	10mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15424	2024
10	ATORVASTATINUM	ATORVASTATINA GEMAX PHARMA 20 mg	film-coated tablets	20mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15425	2024
11	ATORVASTATINUM	ATORVASTATINA GEMAX PHARMA 40 mg	film-coated tablets	40mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15426	2024
12	ATORVASTATINUM	ATORVASTATINA GEMAX PHARMA 80 mg	film-coated tablets	80mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15427	2024
13	BENZYLpenicillinum	PENICILINA G SODICA FRESENIUS KABI 1000000 IU	powder for solution for injection/infusion	1000000IU	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	15412	2024
14	BORTEZOMIBUM	BORTEZOMIB DR. REDDY'S 2.5 mg/ml	solution for injection	2.5mg/ml	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15523	2024
15	BRIMONIDINUM	LUMOBRY 0.25 mg/ml	eye drops, solution	0.25mg/ml	BAUSCH+ LOMB IRELAND LIMIT	IRELAND	15476	2024
16	CALCII GLUCONAS	GLUCONAT DE CALCIU HAMELN 95 mg/ml	solution for injection	95 mg/ml	HAMELN PHARMA GMBH	GERMANY	15480	2024
17	CEFAZOLINUM	ZOLINEF 1 g	powder for solution for injection/infusion	1g	MEDOCHEMIE ROMANIA S.R.L.	ROMANIA	15393	2024
18	CLARITHROMYCINUM	KLABAX 250 mg/5 ml	granules for oral suspension	250mg/5ml	TERAPIA S.A.	ROMANIA	15473	2024
19	CLARITHROMYCINUM	KLABAX 125 mg/5 ml	granules for oral suspension	125mg/5ml	TERAPIA S.A.	ROMANIA	15472	2024

20	COMBINATIONS	NUTRIFLEX OMEGA SPECIAL NOVO	emulsion for infusion		B. BRAUN MELSUNGEN AG	GERMANY	15442	2024
21	COMBINATIONS	NUTRIFLEX OMEGA PLUS NOVO	emulsion for infusion		B. BRAUN MELSUNGEN AG	GERMANY	15441	2024
22	COMBINATIONS	NUTRIFLEX OMEGA PERI NOVO	emulsion for infusion		B. BRAUN MELSUNGEN AG	GERMANY	15443	2024
23	COMBINATIONS (BECLOMETASONUM+ FORMOTEROLUM)	BECLOMETAZONA/ FORMOTEROL CIPLA 200/6 micrograms per dose	pressurised solution for inhalation	200/6 micrograms/ dose	CIPLA EUROPE NV	BELGIUM	15420	2024
24	COMBINATIONS (BIMATOPROSTUM+ TIMOLOLUM)	VIZIMACO 0.3 mg/ml+5 mg/ml	eye drops, solution	0.3mg/ml+ 5mg/ml	BAUSCH + LOMB IRELAND LIMITED	IRELAND	15422	2024
25	COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	CARAMLO 16 mg/5 mg	tablets	16mg/5mg	ZENTIVA K.S.	THE CZECH REPUBLIC	15399	2024
26	COMBINATIONS (CINARIZINUM+ DIMENHIDRINATUM)	LIVOSTIN 20 mg/40 mg	tablets	20mg/40mg	TERAPIA S.A.	ROMANIA	15419	2024
27	COMBINATIONS (DUTASTERIDUM+ TAMSULOSINUM)	DUTASTERIDA/ TAMSULOSIN STADA 0.5 mg/0.4 mg	capsules	0.5mg/ 0.4 mg	STADA M&D S.R.L.	ROMANIA	15430	2024
28	COMBINATIONS (IBUPROFENUM+ PARACETAMOLUM)	PANADOL DUO 200 mg/500 mg	film-coated tablets	200mg/ 500mg	HALEON ROMANIA S.R.L.	ROMANIA	15474	2024
29	COMBINATIONS (IBUPROFENUM+ PARACETAMOLUM)	NUROFEN DUO MAX 200 mg/500 mg	film-coated tablets	200mg/ 500mg	RECKITT BENCKISER (ROMANIA)	ROMANIA	15482	2024

					S.R.L.			
30	COMBINATIONS (LIDOCAINUM+ EPINEPHRINUM)	LIDENT 20 mg/ml+0.0125 mg/ml	solution for injection in cartridge	20mg/ml+ 0.0125mg/ml	LABORATORIOS NORMON, S.A.	SPAIN	15395	2024
31	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	OLSSA 20 mg/5 mg	film-coated tablets	20mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15448	2024
32	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	OLSSA 40 mg/5 mg	film-coated tablets	40mg/5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15449	2024
33	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	OLSSA 40 mg/10 mg	film-coated tablets	40mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15450	2024
34	COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	CO-AMLESSANEO 5 mg/1.25 mg/5 mg	tablets	5mg/1.25mg/ 5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15459	2024
35	COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	CO-AMLESSANEO 10 mg/2.5 mg/5 mg	tablets	10mg/2.5mg/ 5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15460	2024

36	COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM+ AMLODIPINUM)	CO-AMLESSANEO 10 mg/2.5 mg/10 mg	tablets	10mg/2.5mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15461	2024
37	COMPLEX DE ANTIINHIBITORI AI COAGULARII	FEIBA 100 U/ml	powder and solvent for solution for infusion	100U/ml	BAXALTA INNOVATIONS GMBH	AUSTRIA	15394	2024
38	CYCLOPHOSPHAMIDUM	CICLOFOSFAMIDA ACCORD 200 mg/ml	concentrate for solution for injection/infusion	200mg/ml	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15486	2024
39	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILATE ADAMED 75 mg	capsules	75mg	ADAMED PHARMA S.A.	POLAND	15492	2024
40	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILATE ADAMED 110 mg	capsules	110mg	ADAMED PHARMA S.A.	POLAND	15493	2024
41	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILATE ADAMED 150 mg	capsules	150mg	ADAMED PHARMA S.A.	POLAND	15494	2024
42	DAPTOMYCINUM	DAPTOMICINA DR. REDDY'S 350 mg	powder for solution for injection/infusion	350mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15484	2024
43	DAPTOMYCINUM	DAPTOMICINA DR. REDDY'S 500 mg	powder for solution for injection/infusion	500mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	15485	2024
44	DASATINIBUM	DASATINIB TEVA 20 mg	film-coated tablets	20mg	TEVA B.V.	THE NETHERLANDS	15453	2024

45	DASATINIBUM	DASATINIB TEVA 50 mg	film-coated tablets	50mg	TEVA B.V.	THE NETHERLANDS	15454	2024
46	DASATINIBUM	DASATINIB TEVA 70 mg	film-coated tablets	70mg	TEVA B.V.	THE NETHERLANDS	15455	2024
47	DASATINIBUM	DASATINIB TEVA 80 mg	film-coated tablets	80mg	TEVA B.V.	THE NETHERLANDS	15456	2024
48	DASATINIBUM	DASATINIB TEVA 100 mg	film-coated tablets	100mg	TEVA B.V.	THE NETHERLANDS	15457	2024
49	DASATINIBUM	DASATINIB ZENTIVA 20 mg	film-coated tablets	20mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15444	2024
50	DASATINIBUM	DASATINIB ZENTIVA 50 mg	film-coated tablets	50mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15445	2024
51	DASATINIBUM	DASATINIB ZENTIVA 70 mg	film-coated tablets	70mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15446	2024
52	DASATINIBUM	DASATINIB ZENTIVA 100 mg	film-coated tablets	100mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15447	2024
53	DEXAMETHASONUM	ETACORTILEN 1.5 mg/ml	eye drops, solution	1.5mg/ml	SIFI S.P.A.	ITALY	15481	2024
54	DEXKETOPROFENUM	DEKENOR 50 mg/2 ml	solution for injection/infusion	50mg/2ml	KRKA, D.D., NOVO MESTO	SLOVENIA	15452	2024
55	DICLOFENACUM	DICLOFENAC SLAVIA 50 mg/g	gel	50mg/g	SLAVIA PHARM S.R.L.	ROMANIA	15413	2024
56	DIMETHYL FUMARATE	DIMETIL FUMARAT GEDEON RICHTER 120 mg	gastroresistant capsules	120mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	15516	2024

57	DIMETHYL FUMARATE	DIMETIL FUMARAT GEDEON RICHTER 120 mg	gastroresistant capsules	240mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	15517	2024
58	EMPAGLIFLOZINUM	GLUSOD 10 mg	film-coated tablets	10mg	MEDOCHEMIE LTD.	CYPRUS	15397	2024
59	EMPAGLIFLOZINUM	GLUSOD 25 mg	film-coated tablets	25mg	MEDOCHEMIE LTD.	CYPRUS	15398	2024
60	ENTECAVIRUM	ENTECAVIR SANIENCE 0.5 mg	film-coated tablets	0.5mg	SANIENCE S.R.L.	ROMANIA	15414	2024
61	ENTECAVIRUM	ENTECAVIR SANIENCE 1 mg	film-coated tablets	1mg	SANIENCE S.R.L.	ROMANIA	15415	2024
62	ENZALUTAMIDUM	ENZALUTAMIDA ACCORD 40 mg	soft capsules	40mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15505	2024
63	EPTIFIBATIDUM	EPTIFIBATIDA ROMPHARM 0.75 mg/ml	solution for infusion	0.75mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	15436	2024
64	EPTIFIBATIDUM	EPTIFIBATIDA ROMPHARM 2 mg/ml	solution for injection	2mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	15437	2024
65	ERLOTINIBUM	ERLOTINIB VIATRIS 50 mg	film-coated tablets	50mg	VIATRIS LIMITED	IRELAND	15405	2024
66	ERLOTINIBUM	ERLOTINIB VIATRIS 100 mg	film-coated tablets	100mg	VIATRIS LIMITED	IRELAND	15406	2024
67	ERLOTINIBUM	ERLOTINIB VIATRIS 150 mg	film-coated tablets	150mg	VIATRIS LIMITED	IRELAND	15407	2024
68	FERRI CARBOXYMALTOSUM	CARBOXIMALTOZA FERICA TEVA 50 mg/ml	dispersion for injection/infusion	50mg/ml	TEVA B.V.	THE NETHERLANDS	15411	2024

69	FROVATRIPTANUM	AVORAN 2.5 mg	film-coated tablets	2.5mg	BESTA MED LTD.	BULGARIA	15416	2024
70	GEFITINIBUM	GEFITINIB ACCORD 250 mg	film-coated tablets	250mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	15421	2024
71	HEPARINUM	HEPARINA SODICA ROVI 5000 IU/ml	solution for injection	500IU/ml	ANISAPHARM DISTRIBUTION S.R.L.	ROMANIA	15512	2024
72	HYDROCORTISONUM	HIDROCORTIZON ATB 10 mg	tablets	10mg	ANTIBIOTICE SA	ROMANIA	15518	2024
73	IBUPROFENUM	DOLGIT 50 mg/g	gel	50mg/g	HWI PHARMA SERVICES GMBH	GERMANY	15418	2024
74	IBUPROFENUM	IBUPROFEN ALKALOID-INT 50 mg/g	gel	50mg/g	ALKALOID-INT D.O.O.	SLOVENIA	15439	2024
75	IBUPROFENUM	IBUTOP 50 mg/g	cream	50mg/g	HWI PHARMA SERVICES GMBH	GERMANY	15490	2024
76	IMIPENEMUM+ CILASTATINUM	IMIPENEM/CILASTATIN STERISCIENCE 500 mg/500 mg	powder for solution for infusion	500mg/500mg	STERISCIENCE B.V.	THE NETHERLANDS	15507	2024
77	INOSINUM	VIRUXAN COPII 50 mg/ml	syrup	50mg/ml	EWOPHARMA INTERNATIONAL , S.R.O.	SLOVAKIA	15458	2024
78	KETOCONAZOLUM	KETOCONAZOL DR. MAX 20 mg/g	shampoo	20mg/g	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	15396	2024
79	LENALIDOMIDUM	LENALIDOMIDA TEVA 5 mg	capsules	5mg	TEVA B.V.	THE NETHERLANDS	15495	2024



80	LENALIDOMIDUM	LENALIDOMIDA TEVA 10 mg	capsules	10mg	TEVA B.V.	THE NETHERLANDS	15496	2024
81	LENALIDOMIDUM	LENALIDOMIDA TEVA 15 mg	capsules	15mg	TEVA B.V.	THE NETHERLANDS	15497	2024
82	LENALIDOMIDUM	LENALIDOMIDA TEVA 20 mg	capsules	20mg	TEVA B.V.	THE NETHERLANDS	15498	2024
83	LEVONORGESTRELUM	APREG 1.5 mg	tablets	1.5mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15463	2024
84	LORAZEPAMUM	TEMELOR 4 mg/ml	solution for injection	4mg/ml	MEDOCHEMIE LTD.	CYPRUS	15403	2024
85	METFORMINUM	METFORMIN TERAPIA 500 mg	prolonged-release tablets	500mg	TERAPIA S.A.	ROMANIA	15477	2024
86	METFORMINUM	METFORMIN TERAPIA 750 mg	prolonged-release tablets	750mg	TERAPIA S.A.	ROMANIA	15478	2024
87	METFORMINUM	METFORMIN TERAPIA 1000 mg	prolonged-release tablets	1000mg	TERAPIA S.A.	ROMANIA	15479	2024
88	METOCLOPRAMIDUM	METOCLOPRAMID NORIDEM 5 mg/ml	solution for injection	5mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	15423	2024
89	MOXIFLOXACINUM	ERELAN 400 mg	film-coated tablets	400mg	MEDOCHEMIE LTD.	CYPRUS	15404	2024
90	NATRII CHLORIDUM	APTAPHARMA SODIUM CHLORIDE 9 mg/ml	solution for infusion	9mg/ml	APTA MEDICA INTERNACIONA L D.O.O.	SLOVENIA	15504	2024
91	OCTREOTIDUM	OCTREOTIDA TEVA 10 mg	prolonged-release powder and solvent for suspension for	10mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	15400	2024

			injection					
92	OCTREOTIDUM	OCTREOTIDA TEVA 20 mg	prolonged-release powder and solvent for suspension for injection	20mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	15401	2024
93	OCTREOTIDUM	OCTREOTIDA TEVA 30 mg	prolonged-release powder and solvent for suspension for injection	30mg	TEVA PHARMACEUTIC ALS S.R.L.	ROMANIA	15402	2024
94	OCTREOTIDUM	OCTREOTIDA ROMPHARM 0.1 mg/ml	solution for injection/infusion	0.1mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	15506	2024
95	OMEPRAZOLUM	HELANT 20 mg	capsules	20mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	15462	2024
96	OMEPRAZOLUM	LAPPOXO 10 mg/15 ml	concentrate and solvent for solution for infusion	10mg/15ml	ALKALOID - INT D.O.O.	SLOVENIA	15487	2024
97	OMEPRAZOLUM	LAPPOXO 20 mg/15 ml	concentrate and solvent for solution for infusion	20mg/15ml	ALKALOID - INT D.O.O.	SLOVENIA	15488	2024
98	PALIPERIDONUM	PALIPERIDONA STADA 25 mg	prolonged release suspension for injection in pre- filled syringe	25mg	STADA M&D S.R.L.	ROMANIA	15499	2024

99	PALIPERIDONUM	PALIPERIDONA STADA 50 mg	prolonged release suspension for injection in pre- filled syringe	50mg	STADA M&D S.R.L.	ROMANIA	15500	2024
100	PALIPERIDONUM	PALIPERIDONA STADA 75 mg	prolonged release suspension for injection in pre- filled syringe	75mg	STADA M&D S.R.L.	ROMANIA	15501	2024
101	PALIPERIDONUM	PALIPERIDONA STADA 100 mg	prolonged release suspension for injection in pre- filled syringe	100mg	STADA M&D S.R.L.	ROMANIA	15502	2024
102	PALIPERIDONUM	PALIPERIDONA STADA 150 mg	prolonged release suspension for injection in pre- filled syringe	150mg	STADA M&D S.R.L.	ROMANIA	15503	2024
103	PAROXETINUM	PAROXETINA TEVA 10 mg	film-coated tablets	10mg	TEVA B.V.	THE NETHERLANDS	15408	2024
104	PAROXETINUM	PAROXETINA TEVA 20 mg	film-coated tablets	20mg	TEVA B.V.	THE NETHERLANDS	15409	2024
105	PAROXETINUM	PAROXETINA TEVA 30 mg	film-coated tablets	30mg	TEVA B.V.	THE NETHERLANDS	15410	2024
106	HERBS (EXTRACT DE IEDERA)	HERBION IEDERA	lozenges	35mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15440	2024
107	HERBS (PASSION FLOWER HERBAL EXTRACT)	SEDISTRESS 500 mg	film-coated tablets	500mg	TILMAN S.A.	BELGIUM	15491	2024

108	HERBS (COMFREY/ SYMPHYTUM OFFICINALE)	FLEXIVERT	cream			DR. THEISS NATURWAREN GMBH	GERMANY	15515	2024
109	POSACONAZOLUM	POSACONAZOL VIATRIS 40 mg/ml	oral suspension	40mg/ml		VIATRIS LIMITED	IRELAND	15431	2024
110	POSACONAZOLUM	POSACONAZOL STADA 100 mg	gastroresistant tablets	100mg		STADA M&D S.R.L.	ROMANIA	15470	2024
111	PREGABALINUM	SIRANALEN 20 mg/ml	oral solution	20mg/ml		MEDOCHEMIE LTD.	CYPRUS	15514	2024
112	RILMENIDINUM	RILMENIDINA GRINDEKS 1 mg	tablets	1mg		AS GRINDEKS	LATVIA	15451	2024
113	ROCURONIUM BROMIDE	ROCURONIUM ROMPHARM 10 mg/ml	solution for injection/infusion	10mg/ml		ROMPHARM COMPANY S.R.L.	ROMANIA	15438	2024
114	SERTRALINUM	SERTRALINA GEMAX PHARMA 50 mg	film-coated tablets	50mg		GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15434	2024
115	SERTRALINUM	SERTRALINA GEMAX PHARMA100 mg	film-coated tablets	100mg		GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	15435	2024
116	SITAGLIPTINUM	SITAGLIPTINA IASIS 25 mg/ml	oral solution	25mg/ml		IASIS PHARMACEUTIC ALS HELLAS S.A.	GREECE	15475	2024
117	SUGAMMADEXUM	AREVERSIN 100 mg/ml	solution for injection	100mg/ml		PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	AUSTRIA	15508	2024
118	SUNITINIBUM	SUNITINIB SANDOZ 12.5 mg	capsules	12.5mg		SANDOZ PHARMACEUTIC ALS S.R.L.	ROMANIA	15464	2024

119	SUNITINIBUM	SUNITINIB SANDOZ 25 mg	capsules	25mg	SANDOZ PHARMACEUTIC ALS S.R.L.	ROMANIA	15465	2024
120	SUNITINIBUM	SUNITINIB SANDOZ 37.5 mg	capsules	37.5mg	SANDOZ PHARMACEUTIC ALS S.R.L.	ROMANIA	15466	2024
121	SUNITINIBUM	SUNITINIB SANDOZ 50 mg	capsules	50mg	SANDOZ PHARMACEUTIC ALS S.R.L.	ROMANIA	15467	2024
122	TICAGRELOR	TICAGRELOR MSN 60 mg	film-coated tablets	60mg	MSN LABS EUROPE LIMITED	MALTA	15428	2024
123	TICAGRELOR	TICAGRELOR MSN 90 mg	film-coated tablets	90mg	MSN LABS EUROPE LIMITED	MALTA	15429	2024
124	TICAGRELOR	CROALCRIL 60 mg	film-coated tablets	60mg	MEDOCHEMIE LTD.	CYPRUS	15432	2024
125	TICAGRELOR	CROALCRIL 90 mg	film-coated tablets	90mg	MEDOCHEMIE LTD.	CYPRUS	15433	2024
126	TIGECYCLINUM	TIGECICLINA APTAPHARMA 50 mg	powder for solution for infusion	50mg	APTA MEDICA INTERNACIONA L D.O.O.	SLOVENIA	15513	2024
127	ZINCI OROTAS	ZINKOROT 25 mg	tablets	25mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	15471	2024

## EMA centrally authorised medicinal products notified for marketing in Romania during the 2<sup>nd</sup> quarter of 2024

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	AZTREONAMUM+ AVIBACTAMUM	EMBLAVEO 1.5 g/0.5 g	powder for concentrate for solution for infusion	1.5g/0.5g	PFIZER EUROPE MA EEIG	BELGIUM	1808	2024
2	CAPIVASERTIBUM	TRUQAP 160 mg	film-coated tablets	160mg	ASTRAZENECA AB	SWEDEN	1820	2024
3	CAPIVASERTIBUM	TRUQAP 200 mg	film-coated tablets	200mg	ASTRAZENECA AB	SWEDEN	1820	2024
4	DANICOPANUM	VOYDEYA 50 mg+100 mg	film-coated tablets	50mg+100mg	ALEXION EUROPE SAS	FRANCE	1801	2024
5	DANICOPANUM	VOYDEYA 100 mg	film-coated tablets	100mg	ALEXION EUROPE SAS	FRANCE	1801	2024
6	EFANESOCTOCOGUM ALFA	ALTUVOCT 250 IU	powder and solvent for solution for injection	250IU	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	SWEDEN	1824	2024
7	EFANESOCTOCOGUM ALFA	ALTUVOCT 500 IU	powder and solvent for solution for injection	500IU	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	SWEDEN	1824	2024
8	EFANESOCTOCOGUM ALFA	ALTUVOCT 750 IU	powder and solvent for solution for injection	750IU	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	SWEDEN	1824	2024

9	EFANESOCTOCOGUM ALFA	ALTUVOCT 1000 IU	powder and solvent for solution for injection	1000IU	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	SWEDEN	1824	2024
10	EFANESOCTOCOGUM ALFA	ALTUVOCT 2000 IU	powder and solvent for solution for injection	2000IU	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	SWEDEN	1824	2024
11	EFANESOCTOCOGUM ALFA	ALTUVOCT 3000 IU	powder and solvent for solution for injection	3000IU	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	SWEDEN	1824	2024
12	EFANESOCTOCOGUM ALFA	ALTUVOCT 4000 IU	powder and solvent for solution for injection	4000IU	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	SWEDEN	1824	2024
13	IPTACOPANUM	FABHALTA 200 mg	capsules	200mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1802	2024
14	USTEKINUMABUM	PYZCHIVA 45 mg	solution for injection in pre-filled syringe	45mg/0.5ml	SAMSUNG BIOEPIS NL B.V.	THE NETHERLANDS	1801	2024
15	USTEKINUMABUM	PYZCHIVA 90 mg	solution for injection in pre-filled syringe	90mg/ml	SAMSUNG BIOEPIS NL B.V.	THE NETHERLANDS	1801	2024
16	USTEKINUMABUM	PYZCHIVA 130 mg	concentrate for solution for infusion	130mg	SAMSUNG BIOEPIS NL B.V.	THE NETHERLANDS	1801	2024
17	LIVE ATTENUATED INFLUENZA VACCINE	FLUENZ	nasal spray, suspension		ASTRAZENECA AB	SWEDEN	1816	2024