

ROMANIA

Newsletter

Year 18, No. 2 (70), 2nd quarter of 2016

*National Agency for
Medicines
and
Medical Devices*

Medicinal product batches recalled during the 2nd quarter of 2016

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 1st quarter of 2016

Medicinal products authorised for marketing during the 1st quarter of 2016

Medicinal products authorised through centralised procedure by the EMA, notified for marketing in Romania during the 1st quarter of 2016

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Medicinal product batches recalled during the 2nd quarter of 2016

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for recall	Proposed action	Date for recall
1	BIOPAROX	Oromucosal spray	50 mg/ 10 ml	fusafungine	Lab. Servier Industrie, France/Lab. Servier, France	all batches	EMA decision no. 227560/2016 on recall of marketing authorisations for medicinal products containing fusafungine	Recall and destruction	08.04.2016
2	ANGHIRO L	Tablets	3,25 mg	plants	Biofarm SA	01154071, 05155028, 06155279, 08155733	quality noncompliance of tablets under parameter „colour”	Voluntary recall and destruction	21.04.2016
3	ZALDIAR	Prolonged- release film- coated tablets	37.5 mg/ 325 mg	tramadol/ paracetamol	Grunenthal GmbH, GERMANY/ Stada Arzneimittel Ag, Germany	00171F, 00172F, 00433F, 00434F, 00452F, 00453F, 00454F, 00167G, 00168G, 00169G	Product whose 1-year shelf life (as shown in Order of the Minister of Health no. 1810/2006) has expired after NAMMD approval of transfer of marketing authorisation (MA) no. 5186/2005/01 from Grunenthal GmbH, Germany to Stada Arzneimittel	Voluntary recall and destruction	09.05.2016
4	OROFAR	soft capsules	1 mg/1 mg	COMBINATI ONS	RP Scherer GmbH, & Co, Germany/Novartis Consumer Health GmbH, Germany	A8548/1, A9648/1	Product whose 2-year shelf life (as shown in Order of the Minister of Health no. 279/2005) has expired after NAMMD approval of amendment of MA no. 543/2008/01 of 30.04.2014 and 27.06.2014	Voluntary recall and destruction	11.05.2016

5	VIDOTIN	tablets	4 mg	perindopril	Gedeon Richter Romania SA	H44088A 1, H44088A 2, H5A001A 1, H5A001D 1	Within the ongoing stability study, after 3 months, an Outside-of-Specification (OOS) result has been obtained upon dosage of active substance perindopril tert-butylamine	Voluntary recall and destruction	12.05.2016
6	CONCOR COR	film-coated tablets	2.5 mg	bisoprolol	Merck KGAA, Germany	all batches with MA no. 8277/2006/02	product whose 2-year shelf life has expired (as shown in Order of the Minister of Health no. 279/2005) following renewal of the marketing authorisation, as approved by the NAMMD on 21.01.2014	Voluntary recall and destruction	24.05.2016
7	CONCOR COR	film-coated tablets	5 mg	bisoprolol	Merck KGAA, Germany	all batches with MA no. 8278/2006/02	product whose 2-year shelf life has expired (as shown in Order of the Minister of Health no. 279/2005) after renewal of the marketing authorisation, as approved by the NAMMD on 21.01.2014	Voluntary recall and destruction	24.05.2016
8	CONCOR COR	film-coated tablets	10 mg	bisoprolol	Merck KGAA, Germany	all batches with MA no. 8279/2006/02	product whose 2-year shelf life has expired (as shown in Order of the Minister of Health no. 279/2005) after renewal of the marketing authorisation, as approved by the NAMMD on 21.01.2014	Voluntary recall and destruction	24.05.2016
9	AMLODIPI N VIM SPECTRUM	tablets	5 mg	amlodipine	Vim Spectrum S.R.L.	27 045, 27 046, 27 047, 27 048, 27 049, 27 050	Product whose one-year term after discontinuation of renewal of MA no. 6893/2006/01 shall expire on 02.10.2016,	Voluntary recall and destruction	02.06.2016

10	AMLODIPI N VIM SPECTRU M	tablets	10 mg	amlodipine	Vim Spectrum S.R.L	28 036, 28 037, 28 038	Products whose one-year term after discontinuation of renewal of MA no. 6894/2006/01 shall expire on 02.10.2016 the product has been manufactured with artworks based on previous MAs during a period which surpasses 6 months following their renewal (as approved by the NAMMD on 12.03.2015)	Voluntary recall and destruction	02.06.2016
11	BRUFEN RETARD	prolonged- release tablets	400 mg	ibuprofen	Abbvie Deutschland GmbH & Co. KG, GERMANY/BGP Products AB, Sweden	58009PC , 58060PC , 60301PC , 60302PC	the product has been manufactured with artworks based on previous MAs during a period which surpasses 6 months following their renewal (as approved by the NAMMD on 12.03.2015)	Recall and destruction	02.06.2016
12	BRUFEN RETARD	prolonged- release tablets	800 mg	ibuprofen	Abbvie Deutschland GmbH & Co. KG, GERMANY/BGP Products AB, Sweden	603015PC, 60316PC, 60314PC, 60313PC	the product has been manufactured with artworks based on previous MAs during a period which surpasses 6 months following their renewal (as approved by the NAMMD on 12.03.2015)	Recall and destruction	02.06.2016
13	LAMISIL	cream	10 mg/g	terbinafine	Novartis consumer HealthGmb, Germany	M02200A , M02196A, M01304A , M01686A , M01544A , M01942C, M01685D, M01077C, M00963A, M00377A, M00376E, L04390B, L03598B	product whose 2-year shelf life has expired (as shown in Order of the Minister of Health no. 279/2005) following NAMMD approval on 28.05.2014 of amendments to MA no. 5446/2005/01	Voluntary recall and destruction	06.06.2016

14	EGIRAMLO N	capsules	5 mg/5 mg	ramipril+ amlodipine	Egis Pharmaceuticals PLC, Hungary	all batches	medicinal product for which the representation has submitted to the Ministry of Health application no. 17038/10.03.2016 for removal from CaNaMed, these not being anymore found on the list of reimbursed medicinal products of the NHIH medicinal product for which the representation has submitted to the Ministry of Health application no. 17038/10.03.2016 for removal from CaNaMed, these not being anymore found on the list of reimbursed medicinal products of the NHIH	Recall and destruction	21.06.2016
15	EGIRAMLO N	capsules, box x 30	5 mg/10mg	ramipril+ amlodipine	Egis Pharmaceuticals PLC, Hungary	all batches with MA no. 4497/2012/02	medicinal product for which the representation has submitted to the Ministry of Health application no. 17038/10.03.2016 for removal from CaNaMed, these not being anymore found on the list of reimbursed medicinal products of the NHIH	Recall and destruction	21.06.2016
16	EGIRAMLO N	capsules, box x 30	10 mg/ 10 mg	ramipril+ amlodipine	Egis Pharmaceuticals PLC, Hungary	all batches with MA no. 4499/ 2012/02	medicinal product for which the representation has submitted to the Ministry of Health application no. 17038/10.03.2016 for removal from CaNaMed, these not being anymore found on the list of reimbursed medicinal products of the NHIH	Recall and destruction	21.06.2016

**Applications for marketing authorisation/marketing
authorisation renewal submitted to the NAMMD during the
1st quarter of 2016**

During the 1st quarter of 2016, **161** marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

- A02 - DRUGS FOR ACID RELATED DISORDERS
- A03 - DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
- A07 - ANTIDIARRHEALS, INTESTINAL ANTI-INFLAMMATORY/ANTI-INFECTIVE AGENTS
- A10 – DRUGS USED IN DIABETES
- A12 - MINERAL SUPPLEMENTS
- B01 – ANTITHROMBOTIC AGENTS
- C02 - ANTIHYPERTENSIVES
- C07 – BETA BLOCKING AGENTS
- C08 - CALCIUM CHANNEL BLOCKERS
- C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
- C10 - LIPID MODIFYING AGENTS
- D01 - ANTIFUNGALS FOR DERMATOLOGICAL USE
- D10 - ANTI-ACNE PREPARATIONS
- G02 - OTHER GYNECOLOGICALS
- G03 - SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
- G04 - UROLOGICALS
- H03 - THYROID THERAPY
- J01 - ANTIBACTERIALS FOR SYSTEMIC USE
- J02 - ANTIMYCOTICS FOR SYSTEMIC USE
- J05 - ANTIVIRALS FOR SYSTEMIC USE
- L01 - ANTINEOPLASTIC AGENTS
- L02 – ENDOCRINE THERAPY
- M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
- M02 - TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
- M05 - DRUGS FOR TREATMENT OF BONE DISEASES
- N02 - ANALGESICS
- N03 - ANTIEPILEPTICS

N04 – ANTI-PARKINSON DRUGS
N05 - PSYCHOLEPTICS
N06 - PSYCHOANALEPTICS
N07 – OTHER NERVOUS SYSTEM DRUGS
R03 - DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
R05 - COUGH AND COLD PREPARATIONS
R06 – ANTIHISTAMINES FOR SYSTEMIC USE
R07 - OTHER RESPIRATORY SYSTEM PRODUCTS
S01 - OPHTHALMOLOGICALS
V03 - ALL OTHER THERAPEUTIC PRODUCTS
V08 – CONTRAST MEDIA
XRN – HOMEOPATHIC PRODUCTS

Medicinal products authorised for marketing during the 1st quarter of 2016

INN	Invented name	Pharmaceutical form	Strength	MAH	Country	MA number		
ACARBOSUM	GLUCOBAY 50	TABLETS	50mg	BAYER PHARMA AG	GERMANY	8672	2016	01
ACARBOSUM	GLUCOBAY 100	TABLETS	100mg	BAYER PHARMA AG	GERMANY	8673	2016	01
ACIDUM ACETYLSALICYLICUM	ASAPRIN CARDIO 100 mg	GASTRORESISTANT TABLETS	100mg	AC HELCOR PHARMA S.R.L.	ROMANIA	8516	2016	01
ACIDUM ACETYLSALICYLICUM	ASPENTER 75 mg	GASTRORESISTANT TABLETS	75mg	TERAPIA S.A.	ROMANIA	8517	2016	01
ACIDUM IBANDRONICUM	ACID IBANDRONIC FRESENIUS KABI 3 mg	SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	3mg	FRESENIUS KABI ROMANIA SRL.	ROMANIA	8561	2016	01
ACIDUM RISEDRONICUM	RISEDRONAT AUROBINDO 75 mg	FILM-COATED TABLETS	75mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8601	2016	01
ACIDUM VALPROICUM + SARURI	ORFIRIL LONG 150 mg	PROLONGED-RELEASE CAPSULES	150mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	8677	2016	01
ACIDUM VALPROICUM + SARURI	ORFIRIL LONG 300 mg	PROLONGED-RELEASE CAPSULES	300mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	8678	2016	01
ACIDUM VALPROICUM + SARURI	ORFIRIL LONG 500 mg	MINIPROLONGED-RELEASE TABLETS	500mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	8679	2016	01
ACIDUM VALPROICUM + SARURI	ORFIRIL LONG 1000 mg	MINIPROLONGED-RELEASE TABLETS	1000mg	DESITIN ARZNEIMITTEL GMBH	GERMANY	8680	2016	01
ALBENDAZOLUM	DUADOR 200 mg	FILM-COATED TABLETS	200mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8654	2016	01
ALBENDAZOLUM	ALBENDAZOL VIM SPECTRUM 200 mg	TABLETS	200mg	VIM SPECTRUM S.R.L.	ROMANIA	8525	2016	01

ALFACALCIDOLUM	ONE-ALPHA 2micrograms/ml	SOLUTION FOR INJECTION	2micro grams/ ml	LEO PHARMA A/S	DENMARK	8595	2016	01
AMBAZONUM	FARINGOSEPT MIERE SI LAMAIE	ORODISPERSIBLE TABLETS		TERAPIA S.A.	ROMANIA	8549	2016	01
AMBAZONUM	FARINGOSEPT FRUCTE DE PADURE	ORODISPERSIBLE TABLETS		TERAPIA S.A.	ROMANIA	8550	2016	01
AMBAZONUM	FARINGOSEPT VANILIE	ORODISPERSIBLE TABLETS		TERAPIA S.A.	ROMANIA	8551	2016	01
AMBAZONUM	FARINGOSEPT CAFEA	ORODISPERSIBLE TABLETS		TERAPIA S.A.	ROMANIA	8552	2016	01
AMFEPRAMONUM	REGENON 25mg	SOFT CAPSULES	25mg	TEMMLER PHARMA GMBH & CO. KG	GERMANY	8699	2016	01
AMFEPRAMONUM	REGENON RETARD 60mg	PROLONGED- RELEASE CAPSULES	60mg	TEMMLER PHARMA GMBH & CO. KG	GERMANY	8700	2016	01
AMLODIPINUM	ALMACOR 5mg	TABLETS	5mg	ANTIBIOTICE S.A.	ROMANIA	8704	2016	01
AMLODIPINUM	ALMACOR 10mg	TABLETS	10mg	ANTIBIOTICE S.A.	ROMANIA	8705	2016	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOKSIKLA V QUICKTAB 625mg	ORODISPERSIBLE TABLETS	625mg	SANDOZ S.R.L.	ROMANIA	8522	2016	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOKSIKLA V QUICKTAB 1000mg	ORODISPERSIBLE TABLETS	1000mg	SANDOZ S.R.L.	ROMANIA	8523	2016	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AUGMENTIN INTRAVENOS 2000mg/200mg	POWDER FOR SOLUTION FOR INFUSION	2000mg/20 0mg	BEECHAM GROUP PLC	GREAT BRITAIN	8740	2016	01
ARIPIRAZOLUM	ARIPIRAZOL CIPLA 5 mg	TABLETS	5mg	CIPLA EU LIMITED	GREAT BRITAIN	8793	2016	01
ARIPIRAZOLUM	ARIPIRAZOL CIPLA 10 mg	TABLETS	10mg	CIPLA EU LIMITED	GREAT BRITAIN	8794	2016	01
ARIPIRAZOLUM	ARIPIRAZOL CIPLA 15 mg	TABLETS	15mg	CIPLA EU LIMITED	GREAT BRITAIN	8795	2016	01

ARIPIRAZOLUM	ARIPIRAZOL CIPLA 30 mg	TABLETS	30mg	CIPLA EU LIMITED	GREAT BRITAIN	8796	2016	01
ATAZANAVIRUM	ATAZANAVIR TEVA 150 mg	CAPSULES	150mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8596	2016	01
ATAZANAVIRUM	ATAZANAVIR TEVA 200 mg	CAPSULES	200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8597	2016	01
ATAZANAVIRUM	ATAZANAVIR TEVA 300 mg	CAPSULES	300mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8598	2016	01
ATOMOXETINUM	ATOMOXETINA ACTAVIS 10 mg	CAPSULES	10mg	ACTAVIS GROUP PTC EHF.	ICELAND	8786	2016	01
ATOMOXETINUM	ATOMOXETINA ACTAVIS 18 mg	CAPSULES	18mg	ACTAVIS GROUP PTC EHF.	ICELAND	8787	2016	01
ATOMOXETINUM	ATOMOXETINA ACTAVIS 25 mg	CAPSULES	25mg	ACTAVIS GROUP PTC EHF.	ICELAND	8788	2016	01
ATOMOXETINUM	ATOMOXETINA ACTAVIS 40 mg	CAPSULES	40mg	ACTAVIS GROUP PTC EHF.	ICELAND	8789	2016	01
ATOMOXETINUM	ATOMOXETINA ACTAVIS 60 mg	CAPSULES	60mg	ACTAVIS GROUP PTC EHF.	ICELAND	8790	2016	01
ATOMOXETINUM	ATOMOXETINA ACTAVIS 80 mg	CAPSULES	80mg	ACTAVIS GROUP PTC EHF.	ICELAND	8791	2016	01
ATORVASTATINUM	ATORVASTATINA MYLAN 10 mg	FILM-COATED TABLETS	10mg	GENERICS (UK) LTD.	GREAT BRITAIN	8475	2016	01
ATORVASTATINUM	ATORVASTATINA MYLAN 20 mg	FILM-COATED TABLETS	20mg	GENERICS (UK) LTD.	GREAT BRITAIN	8476	2016	01
ATORVASTATINUM	ATORVASTATINA MYLAN 40 mg	FILM-COATED TABLETS	40mg	GENERICS (UK) LTD.	GREAT BRITAIN	8477	2016	01
ATORVASTATINUM	ATORVASTATINA MYLAN 80 mg	FILM-COATED TABLETS	80mg	GENERICS (UK) LTD.	GREAT BRITAIN	8478	2016	01
AZATHIOPRINUM	ATSIMUTIN 25 mg	FILM-COATED TABLETS	25mg	PHARMASWISS CESKA REPUBLIKAS.R.O.	THE CZECH REPUBLIC	8473	2016	01

AZATHIOPRINUM	ATSIMUTIN 50 mg	FILM-COATED TABLETS	50mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	THE CZECH REPUBLIC	8474	2016	01
AZITHROMYCINUM	SUMAMED 500 mg	FILM-COATED TABLETS	500mg	PLIVA LJUBLJANA D.O.O.	SLOVENIA	8766	2016	01
AZITHROMYCINUM	SUMAMED 125 mg	FILM-COATED TABLETS	125mg	PLIVA LJUBLJANA D.O.O.	SLOVENIA	8765	2016	01
AZITHROMYCINUM	SUMAMED FORTE 200 mg/5 ml	POWDER FOR SUSP. ORALA	200mg/ 5ml	PLIVA LJUBLIJANA D.O.O.	SLOVENIA	8767	2016	01
BENDAMUSTINUM	BENDAMUSTINA ZENTIVA 2.5 mg/ml	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	2.5mg/ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	8555	2016	01
BENDAMUSTINUM	BENDAMUSTINA ACCORD 2.5 mg/ml	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	2.5mg/ml	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	8509	2016	01
BETAXOLOLUM	BETAX 5 mg/ml	EYE DROPS, SOLUTION	5mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	8520	2016	01
BICALUTAMIDUM	CASODEX 50 mg	FILM-COATED TABLETS	50mg	ASTRAZENECA UK LIMITED	GREAT BRITAIN	8524	2016	01
BILASTINUM	BORENAR 20 mg	TABLETS	20mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	8562	2016	01
BISACODYLUM	MEDIOLAX 5 mg	GASTRORESISTANT PILLS	5mg	ARENA GROUP S.A.	ROMANIA	8521	2016	01
BISOPROLOLUM	BISOPROLOL FUMARAT MYLAN 1.25 mg	FILM-COATED TABLETS	1.25 mg	GENERICS (UK) LIMITED	GREAT BRITAIN	8638	2016	01
BISOPROLOLUM	BISOPROLOL FUMARAT MYLAN 2.5 mg	FILM-COATED TABLETS	2.5 mg	GENERICS (UK) LIMITED	GREAT BRITAIN	8639	2016	01
BISOPROLOLUM	BISOPROLOL FUMARAT MYLAN 5 mg	FILM-COATED TABLETS	5 mg	GENERICS (UK) LIMITED	GREAT BRITAIN	8640	2016	01
BISOPROLOLUM	BISOPROLOL FUMARAT MYLAN	FILM-COATED TABLETS	10 mg	GENERICS (UK) LIMITED	GREAT BRITAIN	8641	2016	01

	10 mg							
BORTEZOMIBUM	BORTEZOMIB SANDOZ 3.5 mg	POWDER FOR SOLUTION FOR INJECTION	3.5mg	SANDOZ S.R.L.	ROMANIA	8642	2016	01
BROMHEXINUM	BROMFLUEX 12 mg	TABLETS	12mg	BIO EEL S.R.L.	ROMANIA	8746	2016	01
BUDESONIDUM	PULMICORT TURBUHALER 200 micrograms/dose	INHALATION POWDER	200microg rams/dose	ASTRAZENECA AB	SWEDEN	8698	2016	01
BUPRENORFINUM	NOPREX 35 micrograms/hour	TRANSDERMAL PATCH	35microgr ams/hour	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	8706	2016	01
BUPRENORFINUM	NOPREX 52.5 micrograms/hour	TRANSDERMAL PATCH	52.5microg rams/ hour	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	8707	2016	01
BUPRENORFINUM	NOPREX 70 micrograms/hour	TRANSDERMAL PATCH	70micro grams/ hour	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	8708	2016	01
BUTYLSCOPOLAMMONII BROMIDUM	BUSCOTIL 10 mg	TABLETS	10mg	ARENA GROUP S.A.	ROMANIA	8644	2016	01
CALCII FOLINAS	FOLINAT DE CALCIU KABI 10 mg/ml	SOLUTION FOR INJECTION/INFUSIO N	10mg/ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	8548	2016	01
CAPECITABINUM	CAPECITABINA FAIR- MED 150 mg	FILM-COATED TABLETS	150mg	FAIR-MED HEALTHCARE GMBH	GERMANY	8624	2016	01
CAPECITABINUM	CAPECITABINA FAIR- MED 500 mg	FILM-COATED TABLETS	500mg	FAIR-MED HEALTHCARE GMBH	GERMANY	8625	2016	01
CARBAMAZEPINUM	NEUROTOP RETARD 600 mg	PROLONGED- RELEASE TABLETS	600mg	GEROT PHARMAZEUTIKA GES.M.B.H.	AUSTRIA	8467	2016	01
CARBAMAZEPINUM	NEUROTOP RETARD 300 mg	PROLONGED- RELEASE TABLETS	300mg	GEROT PHARMAZEUTIKA GES.M.B.H.	AUSTRIA	8466	2016	01
CEFACLORUM	CEFACLOR TERAPIA MR 750	PROLONGED- RELEASE TABLETS	750mg	TERAPIA S.A.	ROMANIA	8757	2016	01

CEFALEXINUM	CEFALEXIN SANDOZ 125 mg/5 ml	GRANULES FOR ORAL SUSPENSION	125mg/ 5ml	SANDOZ S.R.L.	ROMANIA	8633	2016	01
CEFALEXINUM	CEFALEXIN SANDOZ 250 mg/5 ml	GRANULES FOR ORAL SUSPENSION	250mg/ 5ml	SANDOZ S.R.L.	ROMANIA	8634	2016	01
CEFALEXINUM	CEFALEXIN SANDOZ 250 mg	CAPSULES	250mg	SANDOZ S.R.L.	ROMANIA	8635	2016	01
CETIRIZINUM	CETIRIZINA LAROPHARM 10 mg	FILM-COATED TABLETS	10mg	LAROPHARM S.R.L.	ROMANIA	8518	2016	01
CINACALCETUM	CINACALCET SYNTHON 30 mg	TABLETS	30mg	SYNTHON BV	HOLLAND	8589	2016	01
CINACALCETUM	CINACALCET SYNTHON 60 mg	TABLETS	60mg	SYNTHON BV	HOLLAND	8590	2016	01
CINACALCETUM	CINACALCET SYNTHON 960 mg	TABLETS	90mg	SYNTHON BV	HOLLAND	8591	2016	01
CINACALCETUM	CINACALCET SANDOZ 30 mg	FILM-COATED TABLETS	30mg	SANDOZ S.R.L.	ROMANIA	8661	2016	01
CINACALCETUM	CINACALCET SANDOZ 60 mg	FILM-COATED TABLETS	60mg	SANDOZ S.R.L.	ROMANIA	8662	2016	01
CINACALCETUM	CINACALCET SANDOZ 90 mg	FILM-COATED TABLETS	90mg	SANDOZ S.R.L.	ROMANIA	8663	2016	01
CLARITHROMYCINUM	CLAXIRIT 500 mg	PROLONGED- RELEASE TABLETS	500mg	ACTAVIS GROUP PTC EHF.	ICELAND	8538	2016	01
CLOPIDOGRELUM	CLORODEN 75 mg	FILM-COATED TABLETS	75mg	TORRENT PHARMA S.R.L.	ROMANIA	8739	2016	01
CLOTRIMAZOLUM	CLOTRIMAZOL SLAVIA 10 mg/g	CREAM	10mg/g	SLAVIA PHARMA S.R.L.	ROMANIA	8645	2016	01
CODEINUM	FOSFAT DE CODEINA 15 mg	TABLETS	15mg	SINTOFARM S.A.	ROMANIA	8515	2016	01
COMBINATIONS	ADDAMEL	CONCENTRATE FOR SOLUTION FOR INFUSION		FRESENIUS KABI AB	SWEDEN	8744	2016	01
COMBINATIONS	CAPD PERILINE 1.5% F 100	SOLUTION FOR PERITONEAL DIALYSIS	1.5%	INFOMED FLUID S.R.L.	ROMANIA	8651	2016	01
COMBINATIONS	CAPD PERILINE 2.5% F 200	SOLUTION FOR PERITONEAL	2.5%	INFOMED FLUID S.R.L.	ROMANIA	8652	2016	01

		DIALYSIS						
COMBINATIONS	CAPD PERILINE 4% F 400	SOLUTION FOR PERITONEAL DIALYSIS	4%	INFOMED FLUID S.R.L.	ROMANIA	8653	2016	01
COMBINATIONS	PRISMASOL 2 mmole/potassium	SOLUTION FOR HEMODIALYSIS HEMOFILTRATION		GAMBRO LUNDIA AB	SWEDEN	8752	2016	01
COMBINATIONS	PRISMASOL 4 mmole/potassium	SOLUTION FOR HEMODIALYSIS HEMOFILTRATION		GAMBRO LUNDIA AB	SWEDEN	8753	2016	01
COMBINATIONS	CONTROLGAST- DUO 680 mg/80 mg	CHEWABLE TABLETS	680mg/ 80mg	BIOEEL S.R.L.	ROMANIA	8727	2016	01
COMBINATIONS	GRIPPOSTAD ZI	CAPSULES		STADA ARZNEIMITTEL AG	GERMANY	8734	2016	01
COMBINATIONS (AMINOACIZI)	NUTRIFLEX OMEGA SPECIAL	EMULSION FOR INFUSION		B. BRAUN MELSUNGEN AG	GERMANY	8510	2016	01
COMBINATIONS (AMINOACIZI)	NUTRIFLEX OMEGA PLUS	EMULSION FOR INFUSION		B. BRAUN MELSUNGEN AG	GERMANY	8511	2016	01
COMBINATIONS (BECLOMETASONUM+FOR MOTEROLUM)	FOSTER NEXTHALER 200 micrograms/ 6 micrograms	INHALATION POWDER	200microg rams/ 6 micro grams	CHIESI PHARMACEUTICALS GMBH	AUSTRIA	8612	2016	01
COMBINATIONS (BECLOMETASONUM+FOR MOTEROLUM)	FOSTER NEXTHALER 200 micrograms/ 6 micrograms	PRESSURISED INHALATION SOLUTION	200microg rams/ 6micro grams	CHIESI PHARMACEUTICALS GMBH	AUSTRIA	8611	2016	01
COMBINATIONS (BISOPROLOLUM+AMLODI PINUM)	CONCOR AM 5 mg/ 5 mg	TABLETS	5mg/ 5mg	MERCK KGaA	GERMANY	8773	2016	01
COMBINATIONS (BISOPROLOLUM+AMLODI PINUM)	CONCOR AM 10 mg/ 5 mg	TABLETS	10mg/ 5mg	MERCK KGaA	GERMANY	8775	2016	01
COMBINATIONS (BISOPROLOLUM+AMLODI PINUM)	CONCOR AM 5 mg/ 10 mg	TABLETS	5mg/ 10mg	MERCK KGaA	GERMANY	8774	2016	01

COMBINATIONS (BISOPROLOLUM+AMLODI PINUM)	CONCOR AM 10 mg/ 10 mg	TABLETS	10mg/ 10mg	MERCK KGaA	GERMANY	8776	2016	01
COMBINATIONS (BISOPROLOLUM+PERIND OPRILUM)	COSYREL 5 mg/ 5 mg	FILM-COATED TABLETS	5mg/ 5mg	LES LABORATOIRES SERVIER	FRANCE	8468	2016	01
COMBINATIONS (BISOPROLOLUM+PERIND OPRILUM)	COSYREL 5 mg/ 10 mg	FILM-COATED TABLETS	5mg/ 10mg	LES LABORATOIRES SERVIER	FRANCE	8469	2016	01
COMBINATIONS (BISOPROLOLUM+PERIND OPRILUM)	COSYREL 10 mg/5 mg	FILM-COATED TABLETS	10mg/ 5mg	LES LABORATOIRES SERVIER	FRANCE	8470	2016	01
COMBINATIONS (BISOPROLOLUM+PERIND OPRILUM)	COSYREL 10 mg/10 mg	FILM-COATED TABLETS	10mg/ 10mg	LES LABORATOIRES SERVIER	FRANCE	8471	2016	01
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	BUFOMIX EASYHALER 80 micrograms/ 4.5 micrograms/inhalation	INHALATION POWDER	80micro grams/ 4.5microgr ams/ inhalation	ORION CORPORATION	FINLAND	8800	2016	01
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	OREST EASYHALER 80 micrograms/ 4.5 micrograms/inhalation	INHALATION POWDER	80microgr ams/4.5mi crograms/ inhalation	ORION CORPORATION	FINLAND	8801	2016	01
COMBINATIONS (CALCIUM CARBONATE+MAGNESIUM CARBONATE)	ADOCID 680 mg/80 mg	CHEWABLE TABLETS	680mg/ 80mg	BIOEEL S.R.L.	ROMANIA	8785	2016	01
COMBINATIONS (CANDESARTANUM CILEXETIL+HCT)	CANDESARTAN HIDROCLOROTIAZIDA TORRENT 8 mg/12.5 mg	TABLETS	8mg/ 12.5mg	TORRENT PHARMA S.R.L.	ROMANIA	8599	2016	01
COMBINATIONS (CANDESARTANUM CILEXETIL+HCT)	CANDESARTAN HIDROCLOROTIAZIDA TORRENT 16 mg/12.5 mg	TABLETS	16mg/ 12.5mg	TORRENT PHARMA S.R.L.	ROMANIA	8600	2016	01
COMBINATIONS (CEFOPERAZONUM+ SULBACTAMUM)	SULCEF 1000 mg/ 1000 mg	POWDER FOR SOLUTION FOR INJECTION/INFUSIO N	1000mg/10 00mg	MEDOCHEMIE ROMANIA SRL	ROMANIA	8729	2016	01

COMBINATIONS (DIENOGESTUM+ ETINILESTRADIOLUM)	DIENORETTE 2 mg/ 0.03 mg	FILM-COATED TABLETS	2mg/ 0.03mg	EXELTIS MAGYARORSZAG KFT	HUNGARY	8629	2016	01
COMBINATIONS (DIENOGESTUM+ ETINILESTRADIOLUM)	ESYLYA 2 mg/0.03 mg	FILM-COATED TABLETS	2mg/ 0.03mg	HEATON K.S.	THE CZECH REPUBLIC	8560	2016	01
COMBINATIONS (FACTORI DE COAGULARE)	BERIPLEX P/N/ 500 IU	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	500 IU	CSL BEHRING GMBH	GERMANY	8626	2016	01
COMBINATIONS (FACTORI DE COAGULARE)	BERIPLEX P/N/ 1000 IU	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	1000 IU	CSL BEHRING GMBH	GERMANY	8627	2016	01
COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	GESTODEN/ETINILESTRADIOL SANDOZ 75 micrograms/20 micrograms	TABLETS	75micro grams/20micro grams	SANDOZ S.R.L.	ROMANIA	8713	2016	01
COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	GESTODEN/ETINILESTRADIOL SANDOZ 75 micrograms/ 30 micrograms	TABLETS	75micro grams/30 micrograms	SANDOZ S.R.L.	ROMANIA	8714	2016	01
COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	GESTODEN/ETINILESTRADIOL SANDOZ 60 micrograms/ 15 micrograms	FILM-COATED TABLETS	60micro grams/15 micrograms	SANDOZ S.R.L.	ROMANIA	8719	2016	01
COMBINATIONS (IBUPROFENUM+ PSEUDOEFEDRINUM)	OLYTABS 200 mg/ 30 mg	FILM-COATED TABLETS	200mg/ 30mg	DIAPHARM GMBH & CO.KG	GERMANY	8529	2016	01
COMBINATIONS (IBUPROFENUM+ PSEUDOEFEDRINUM)	ADVIL SINUS SI RACEALA 200 mg/ 30 mg (see R01BA52)	SOFT CAPSULES	200mg/ 30mg	PFIZER CORPORATION AUSTRIA GMBH	AUSTRIA	8760	2016	01
COMBINATIONS (IBUPROFENUM+ PSEUDOEFEDRINUM)	ADVIL SINUS SI RACEALA 200 mg /30 mg (see M01AE51)	SOFT CAPSULES	200mg/ 30mg	PFIZER CORPORATION AUSTRIA GMBH	AUSTRIA	8760	2016	01
COMBINATIONS LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM	TRIGELAN 50 mg/ 12.5 mg/200 mg	FILM-COATED TABLETS	50mg/ 12.5mg/ 200mg	G.L. PHARMA GMBH	AUSTRIA	8602	2016	01

COMBINATIONS LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM	TRIGELAN 100 mg/ 25 mg/200 mg	FILM-COATED TABLETS	100mg/ 25mg/ 200mg	G.L. PHARMA GMBH	AUSTRIA	8603	2016	01
COMBINATIONS LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM	TRIGELAN 150 mg/ 37.5 mg/200 mg	FILM-COATED TABLETS	150mg/ 37.5mg/ 200mg	G.L. PHARMA GMBH	AUSTRIA	8604	2016	01
COMBINATIONS LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM	TRIGELAN 200 mg/ 50 mg/200 mg	FILM-COATED TABLETS	200mg/ 50mg/ 200mg	G.L. PHARMA GMBH	AUSTRIA	8605	2016	01
COMBINATIONS (OLMESARTANUM+ AMLODIPINUM+HCT)	INOVUM HCT 20 mg/ 5 mg/12.5 mg	FILM-COATED TABLETS	20mg/ 5mg/ 12.5mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	8618	2016	01
COMBINATIONS (OLMESARTANUM+ AMLODIPINUM+HCT)	INOVUM HCT 40 mg/ 5 mg/12.5 mg	FILM-COATED TABLETS	40mg/ 5mg/ 12.5mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	8619	2016	01
COMBINATIONS (OLMESARTANUM+ AMLODIPINUM+HCT)	INOVUM HCT 40 mg/ 5 mg/25 mg	FILM-COATED TABLETS	40mg/ 5mg/ 25mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	8621	2016	01
COMBINATIONS (OLMESARTANUM+ AMLODIPINUM+HCT)	INOVUM HCT 40 mg/ 10 mg/12.5 mg	FILM-COATED TABLETS	40mg/ 10mg/ 12.5mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	8620	2016	01
COMBINATIONS (OLMESARTANUM+ AMLODIPINUM+HCT)	INOVUM HCT 40 mg/ 10 mg/25 mg	FILM-COATED TABLETS	40mg/ 10mg/ 25mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	8622	2016	01
COMBINATIONS (OLMESARTANUM+ AMLODIPINUM+HCT)	SEVIKAR HCT 20mg/ 5 mg/12.5 mg	FILM-COATED TABLETS	20mg/ 5mg/ 12.5mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	8613	2016	01
COMBINATIONS (OLMESARTANUM+AMLO DIPINUM+HCT)	SEVIKAR HCT 40mg/ 5 mg/12.5 mg	FILM-COATED TABLETS	40mg/ 5mg/ 12.5mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	8614	2016	01

COMBINATIONS (OLMESARTANUM+ AMLODIPINUM+HCT)	SEVIKAR HCT 40mg/ 10 mg/12.5 mg	FILM-COATED TABLETS	40mg/ 10mg/ 12.5mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	8615	2016	01
COMBINATIONS (OLMESARTANUM+ AMLODIPINUM+HCT)	SEVIKAR HCT 40mg/ 5 mg/25 mg	FILM-COATED TABLETS	40mg/ 5mg/ 25mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	8616	2016	01
COMBINATIONS (OLMESARTANUM+ AMLODIPINUM+HCT)	SEVIKAR HCT 40mg/ 10 mg/25 mg	FILM-COATED TABLETS	40mg/ 10mg/ 25mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	8617	2016	01
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	CO-PERINEVA 8 mg/ 2.5 mg	TABLETS	8mg/ 2.5mg	KRKA-POLSKA SP. Z O.O.	POLAND	8499	2016	01
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	CO-PRENESSA 8 mg/2.5mg	TABLETS	8mg/ 2.5mg	KRKA-POLSKA SP. Z O.O.	POLAND	8547	2016	01
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	CO-PERINEVA 2 mg/ 0.625 mg	TABLETS	2mg/0.625 mg	KRKA-POLSKA SP. Z O.O.	POLAND	8545	2016	01
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	CO-PERINEVA 4 mg/ 1.25 mg	TABLETS	4mg/ 1.25mg	KRKA-POLSKA SP. Z O.O.	POLAND	8546	2016	01
COMBINATIONS (SPIRONOLACTONUM+ FUROSEMIDUM)	DIUREX 50/20 mg	CAPSULES	50mg/ 20mg	TERAPIA SA	ROMANIA	8703	2016	01
COMBINATIONS (TRAMADOLUM+ DEXKETOPROFENUM)	SKUDEX 75 mg/ 25 mg	FILM-COATED TABLETS	75mg/ 25mg	MENARINI INTERNATIONAL OPERATION LUXEMBOURG S.A.	LUXEMBOURG	8762	2016	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	DORETA EP 75 mg/ 650 mg	PROLONGED- RELEASE TABLETS	75mg/ 650mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8527	2016	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	TRAMADOL/PARACETA MOL AUROBINDO 37.5 mg/325 mg	FILM-COATED TABLETS	37.5mg/ 325mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8709	2016	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	TRAMADOL/PARACETA MOL SANDOZ 37.5 mg/325 mg	TABLETS	37.5mg/ 325mg	SANDOZ S.R.L.	ROMANIA	8750	2016	01

COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	TRAMADOL/PARACETAMOL SANDOZ 75 mg/650 mg	TABLETS	75mg/ 650mg	SANDOZ S.R.L.	ROMANIA	8751	2016	01
COMBINATIONS(ATORVAS TATINUM+PERINDOPRILUM+ AMLODIPIN)	LIPERTANCE 10 mg/ 5 mg/5 mg	FILM-COATED TABLETS	10mg/ 5mg/ 5mg	LES LABORATOIRES SERVIER	FRANCE	8494	2016	01
COMBINATIONS(ATORVAS TATINUM+PERINDOPRILUM+ AMLODIPIN)	LIPERTANCE 20 mg/ 5 mg/5 mg	FILM-COATED TABLETS	20mg/ 5mg/ 5mg	LES LABORATOIRES SERVIER	FRANCE	8495	2016	01
COMBINATIONS(ATORVAS TATINUM+PERINDOPRILUM+ AMLODIPIN)	LIPERTANCE 20 mg/ 5 mg/10 mg	FILM-COATED TABLETS	20mg/ 5mg/ 10mg	LES LABORATOIRES SERVIER	FRANCE	8496	2016	01
COMBINATIONS(ATORVAS TATINUM+PERINDOPRILUM+ AMLODIPIN)	LIPERTANCE 20 mg/ 10 mg/10 mg	FILM-COATED TABLETS	20mg/10mg g/10mg	LES LABORATOIRES SERVIER	FRANCE	8497	2016	01
COMBINATIONS(ATORVAS TATINUM+PERINDOPRILUM+ AMLODIPIN)	LIPERTANCE 40 mg/ 10 mg/10 mg	FILM-COATED TABLETS	40mg/10mg g/10mg	LES LABORATOIRES SERVIER	FRANCE	8498	2016	01
CYANCOBALAMINUM+FERROSI SULFAS+ACIDUM FOLICUM	FERRO - FOLGAMMA	SOFT CAPSULES		WORWAG PHARMA GMBH & CO. KG	GERMANY	8533	2016	01
DESLORATADINUM	DESLORATADINA CIPLA 5 mg	FILM-COATED TABLETS	5mg	CIPLA EUROPE NV	BELGIUM	8741	2016	01
DESOGESTRELUM	DESOGESTREL SANDOZ 75 micrograms	FILM-COATED TABLETS	75micro grams	SANDOZ S.R.L.	ROMANIA	8537	2016	01
DEXAMETHASONUM	DEXAMETHASON 0.5 mg	TABLETS	0.5mg	CN UNIFARM S.A.	ROMANIA	206	2016	01
DEXAMETHASONUM	DEXAGEL 0.985 mg/g	EYE GEL	0.985 mg/g	PHARMASWISS CESKA REPUBLIKA S.R.O.	THE CZECH REPUBLIC	8799	2016	01
DIAZEPAMUM	DIAZEPAM TERAPIA 10 mg	TABLETS	10mg	TERAPIA S.A.	ROMANIA	8702	2016	01
DICLOFENACUM	DICLOFENAC HELCOR 50 mg	GASTRORESISTANT TABLETS	50mg	A.C. HELCOR PHARMA SRL	ROMANIA	8676	2016	01

DONEPEZILUM	DONEPEZIL TORRENT 5 mg	FILM-COATED TABLETS	5mg	TORRENT PHARMA S.R.L.	ROMANIA	8563	2016	01
DONEPEZILUM	DONEPEZIL TORRENT 10 mg	FILM-COATED TABLETS	10mg	TORRENT PHARMA S.R.L.	ROMANIA	8564	2016	01
DORZOLAMIDUM	DORZOSTILL 20 mg/ml	EYE DROPS, SOLUTION	20mg/ ml	BRUSCHETTINI SRL	ITALY	8528	2016	01
DUTASTERIDUM	MAXTRID 0.5 mg	SOFT CAPSULES	0.5mg	STADA M&D S.R.L.	ROMANIA	8735	2016	01
EPINEPHRINUM	ADRENALINA AGUETTANT 0.1 mg/ml	SOLUTION FOR INJECTION IN PRE- FILLED SYRINGE	0.1mg/ ml	LABORATOIRE AGUETTANT	FRANCE	8630	2016	01
EPLERENONUM	EPLERENONA SANDOZ 25 mg	FILM-COATED TABLETS	25mg	SANDOZ S.R.L.	ROMANIA	8659	2016	01
EPLERENONUM	EPLERENONA SANDOZ 50 mg	FILM-COATED TABLETS	50mg	SANDOZ S.R.L.	ROMANIA	8660	2016	01
ESCITALOPRAMUM	ESCITASAN 10 mg	FILM-COATED TABLETS	10mg	STADA HEMOFARM SRL	ROMANIA	8733	2016	01
ESCITALOPRAMUM	ESCITOTAB 10 mg	FILM-COATED TABLETS	10mg	GENTHON BV	HOLLAND	8539	2016	01
ESCITALOPRAMUM	ESCITOTAB 15 mg	FILM-COATED TABLETS	15mg	GENTHON BV	HOLLAND	8540	2016	01
ESCITALOPRAMUM	ESCITOTAB 20 mg	FILM-COATED TABLETS	20mg	GENTHON BV	HOLLAND	8541	2016	01
ETORICOXIBUM	ETORICOXIB PHARMASWISS 60 mg	FILM-COATED TABLETS	60mg	PHARMASWISS CESKÁ REPUBLIKA S.R.O.	THE CZECH REPUBLIC	8573	2016	01
ETORICOXIBUM	ETORICOXIB PHARMASWISS 90 mg	FILM-COATED TABLETS	90mg	PHARMASWISS CESKÁ REPUBLIKA S.R.O.	THE CZECH REPUBLIC	8574	2016	01
ETORICOXIBUM	ETORICOXIB PHARMASWISS 120 mg	FILM-COATED TABLETS	120mg	PHARMASWISS CESKÁ REPUBLIKA S.R.O.	THE CZECH REPUBLIC	8575	2016	01
FLUCONAZOLUM	FLUCORIC 150 mg	CAPSULES	150mg	TERAPIA SA	ROMANIA	8658	2016	01
FLUCONAZOLUM	FLUCORIC 50 mg	CAPSULES	50mg	TERAPIA SA	ROMANIA	8657	2016	01
FLUCONAZOLUM	FLUCONAZOL SANDOZ	CAPSULES	50mg	SANDOZ S.R.L.	ROMANIA	8647	2016	01

	50 mg							
FLUCONAZOLUM	FLUCONAZOL SANDOZ 150 mg	CAPSULES	150mg	SANDOZ S.R.L.	ROMANIA	8648	2016	01
FLUCONAZOLUM	FLUCONAZOLE TEVA 50 mg	CAPSULES	50mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8781	2016	01
FLUCONAZOLUM	FLUCONAZOLE TEVA 100 mg	CAPSULES	100mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8782	2016	01
FLUCONAZOLUM	FLUCONAZOLE TEVA 150 mg	CAPSULES	150mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8783	2016	01
FLUCONAZOLUM	FLUCONAZOLE TEVA 200 mg	CAPSULES	200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8784	2016	01
FOSINOPRILUM	FOSINOPRIL AUROBINDO 10 mg	TABLETS	10mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8543	2016	01
FOSINOPRILUM	FOSINOPRIL AUROBINDO 20 mg	TABLETS	20mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8544	2016	01
FUROSEMIDUM	FUROSEMID ZENTIVA 40 mg	TABLETS	40mg	ZENTIVA S.A.	ROMANIA	8646	2016	01
FUROSEMIDUM	FUROSEMID MCC 40 mg	TABLETS	40mg	MAGISTRA C&C S.R.L.	ROMANIA	8745	2016	01
GALANTAMINUM	GALSYA 8 mg	PROLONGED- RELEASE CAPSULES	8mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8710	2016	01
GALANTAMINUM	GALSYA 16 mg	PROLONGED- RELEASE CAPSULES	16mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8711	2016	01
GALANTAMINUM	GALSYA 24 mg	PROLONGED- RELEASE CAPSULES	24mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8712	2016	01
GEMCITABINUM	GITRABIN 40 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	40mg/ ml	ACTAVIS GROUP PTC EHF.	ICELAND	8720	2016	01

GEMCITABINUM	GEMCITABINA SUN 10 mg/ml	SOLUTION FOR INFUSION	10mg/ ml	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	8514	2016	01
GLATIRAMER ACETAT	COPAXONE 40 mg/ml	SOLUTION FOR INJECTION IN PRE- FILLED SYRINGE	40mg/ ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8504	2016	01
GLICLAZIDUM	GLICLAZIDA TEVA 60 mg	MODIFIED- RELEASE TABLETS	60mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8587	2016	01
GLICLAZIDUM	GLYCLADA 90 mg	MODIFIED- RELEASE TABLETS	90mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8797	2016	01
HOMEOPATE	MEDICAMENTE HOMEOPATICE GRANULE 1	GRANULES		PLANTEXTRAKT S.R.L.	ROMANIA	8691	2016	01
HYDROCORTISONUM BUTYRATUM	LOCOID CRELO 1 mg/g	CUTANEOUS EMULSION	1mg/g	ASTELLAS PHARMA EUROPE B.V.	HOLLAND	8669	2016	01
HYDROCORTISONUM BUTYRATUM	LOCOID 1 mg/g	CREAM	1mg/g	ASTELLAS PHARMA EUROPE B.V.	HOLLAND	8683	2016	01
HYDROCORTISONUM BUTYRATUM	LOCOID LIPOCREAM 1mg/g	CREAM	1mg/g	ASTELLAS PHARMA EUROPE B.V.	HOLLAND	8684	2016	01
HYDROCORTISONUM BUTYRATUM	LOCOID 1 mg/ml	CUTANEOUS SOLUTION	1mg/ml	ASTELLAS PHARMA EUROPE B.V.	HOLLAND	8701	2016	01
IBUPROFENUM	ANTINEVRALGIC EXPRESS 200 mg	SOFT CAPSULES	200mg	SANOFI - AVENTIS ROMANIA S.R.L.	ROMANIA	8553	2016	01
IBUPROFENUM	ANTINEVRALGIC EXPRESS FORTE 400 mg	SOFT CAPSULES	400mg	SANOFI - AVENTIS ROMANIA S.R.L.	ROMANIA	8554	2016	01
IMATINIBUM	IMATINIB SANDOZ 100 mg	FILM-COATED TABLETS	100mg	SANDOZ S.R.L.	ROMANIA	8535	2016	01
IMATINIBUM	IMATINIB SANDOZ 400 mg	FILM-COATED TABLETS	400mg	SANDOZ S.R.L.	ROMANIA	8536	2016	01
IMUNOGLOBULINA UMANA NORMALA	INTRATECT 100 g/l	SOLUTION FOR INFUSION	100g/l	BIOTEST PHARMA GMBH	GERMANY	8696	2016	01

IMUNOGLOBULINA UMANA NORMALA	INTRATECT 50 g/l	SOLUTION FOR INFUSION	50g/l	BIOTEST PHARMA GMBH	GERMANY	8695	2016	01
INDAPAMIDUM	INDAPAMID MCC 1.5 mg	PROLONGED-RELEASE TABLETS	1.5mg	MAGISTRA C&C S.R.L.	ROMANIA	8756	2016	01
INDAPAMIDUM	INDAPAMID STADA 1.5mg	PROLONGED-RELEASE TABLETS	1.5mg	STADA ARZNEIMITTEL AG	GERMANY	8594	2016	01
IRINOTECANUM	IRINOTESIN 20mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	20mg/ml	ACTAVIS S.R.L.	ROMANIA	8655	2016	01
IRINOTECANUM	IRINOTECAN HOSPIRA 20mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	20mg/ml	HOSPIRA UK LIMITED	GREAT BRITAIN	8481	2016	01
ITRACONAZOLUM	ITRACONAZOL FARMEX 100 mg	CAPSULES	100mg	FARMEX COMPANY S.R.L.	ROMANIA	8690	2016	01
LEFLUNOMIDUM	LEFLUNOMIDA SANDOZ 10 mg	FILM-COATED TABLETS	10 mg	SANDOZ S.R.L.	ROMANIA	8580	2016	01
LEFLUNOMIDUM	LEFLUNOMIDA SANDOZ 20 mg	FILM-COATED TABLETS	20 mg	SANDOZ S.R.L.	ROMANIA	8581	2016	01
LEFLUNOMIDUM	LEFLUNOMIDE ARENA 10 mg	FILM-COATED TABLETS	10mg	ARENA GROUP S.A.	ROMANIA	8724	2016	01
LEFLUNOMIDUM	LEFLUNOMIDE ARENA 20 mg	FILM-COATED TABLETS	20mg	ARENA GROUP S.A.	ROMANIA	8725	2016	01
LEFLUNOMIDUM	LEFLUNOMIDE ARENA 100 mg	FILM-COATED TABLETS	100mg	ARENA GROUP S.A.	ROMANIA	8726	2016	01
LEVOFLOXACINUM	LEVOFLOXACINA SANDOZ 5 mg/ml	SOLUTION FOR INFUSION	5mg/ml	SANDOZ S.R.L.	ROMANIA	8631	2016	01
LEVONORGESTRELUM	ESCAPELLE 1.5 mg	TABLETS	1.5mg	GEDEON RICHTER PLC.	HUNGARY	8697	2016	01
LEVONORGESTRELUM	LEVONORGESTREL ZENTIVA 1500 micrograms	TABLETS	1500 micrograms	ZENTIVA, K.S.	THE CZECH REPUBLIC	8780	2016	01
LIDOCAINUM	LIDOCAINA GRINDEKS 20 mg/ml	SOLUTION FOR INJECTION	20mg/ml	AS GRINDEKS	LATVIA	8798	2016	01

LINEZOLIDUM	LINEZOLID TEVA 2 mg/ml	SOLUTION FOR INFUSION	2mg/ ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8559	2016	01
LINEZOLIDUM	LINEZOLID ACTAVIS 2 mg/ml	SOLUTION FOR INFUSION	2mg/ ml	ACTAVIS GROUP PTC EHF.	ICELAND	8569	2016	01
LINEZOLIDUM	LINEZOLID GLENMARK 600 mg	FILM-COATED TABLETS	600mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	8542	2016	01
LISINOPRILUM	LISINOPRIL ACTAVIS 5 mg	TABLETS	5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8692	2016	01
LISINOPRILUM	LISINOPRIL ACTAVIS 10 mg	TABLETS	10mg	ACTAVIS GROUP PTC EHF.	ICELAND	8693	2016	01
LISINOPRILUM	LISINOPRIL ACTAVIS 20 mg	TABLETS	20mg	ACTAVIS GROUP PTC EHF.	ICELAND	8694	2016	01
LOVASTATINUM	MEDOSTATIN 20 mg	TABLETS	20mg	MEDOCHEMIE LTD.	CYPRUS	8742	2016	01
MEROPENEMUM	MEROPENEM AUROBINDO 500 mg	POWDER FOR SOLUTION FOR INJECTION/INFUSIO N	500mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8556	2016	01
MEROPENEMUM	MEROPENEM AUROBINDO 1 g	POWDER FOR SOLUTION FOR INJECTION/INFUSIO N	1g	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8557	2016	01
MESALAZINUM	PENTASA 1000 mg	SUPPOSITORIES	1000mg	FERRING GMBH	GERMANY	8670	2016	01
METOCLOPRAMIDUM	METOCLOPRAMID 10 mg	TABLETS	10mg	TERAPIA SA	ROMANIA	8519	2016	01
METOPROLOLUM	METOPROLOL SLAVIA 50 mg	TABLETS	50mg	SLAVIA PHARM S.R.L.	ROMANIA	8730	2016	01
METOPROLOLUM	METOPROLOL SLAVIA 100 mg	TABLETS	100mg	SLAVIA PHARM S.R.L.	ROMANIA	8731	2016	01
METOPROLOLUM	BLOXAZOC 25 mg	PROLONGED- RELEASE TABLETS	25mg	KRKA D.D., NOVO MESTO	SLOVENIA	8715	2016	01
METOPROLOLUM	BLOXAZOC 50 mg	PROLONGED- RELEASE TABLETS	50mg	KRKA D.D., NOVO MESTO	SLOVENIA	8716	2016	01

METOPROLOLUM	BLOXAZOC 100 mg	PROLONGED- RELEASE TABLETS	100mg	KRKA D.D., NOVO MESTO	SLOVENIA	8717	2016	01
METOPROLOLUM	BLOXAZOC 200 mg	PROLONGED- RELEASE TABLETS	200mg	KRKA D.D., NOVO MESTO	SLOVENIA	8718	2016	01
MINOXIDILUM	REGAINE FEMINA 50 mg/g	CUTANEOUS FOAM	50mg/g	MCNEIL PRODUCTS LIMITED	GREAT BRITAIN	8628	2016	01
MIRTAZAPINUM	MIRTAZAPINA BLUEFISH 15 mg	ORODISPERSIBLE TABLETS	15mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	8777	2016	01
MIRTAZAPINUM	MIRTAZAPINA BLUEFISH 30 mg	ORODISPERSIBLE TABLTS	30mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	8778	2016	01
MIRTAZAPINUM	MIRTAZAPINA BLUEFISH 45 mg	ORODISPERSIBLE TABLETS	45mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	8779	2016	01
MITOMICINUM	MITOMICINA MEDAC 1mg/ml	INTRAVESICAL POWDER FOR SOLUTION FOR INJECTION/INFUSIO N OR SOLUTION	1mg/ml	MEDAC GMBH	GERMANY	8664	2016	01
MITOMICINUM	MITOMICINA MEDAC 20 mg	POWDER AND SOLVENT FOR INTRAVESICAL SOLUTION	20mg	MEDAC GMBH	GERMANY	8665	2016	01
MITOMICINUM	MITOMICINA MEDAC 40 mg	POWDER AND SOLVENT FOR INTRAVESICAL SOLUTION	40mg	MEDAC GMBH	GERMANY	8666	2016	01
MITOXANTRONUM	ONKOTRONE 2 mg/ml	CONCENTRATE FOR SOLUTION FOR INJECTION	2mg/ml	BAXTER ONCOLOGY GMBH	GERMANY	8636	2016	01
MYCOPHENOLATUM	MYFORTIC 180 mg	GASTRORESISTANT TABLETS	180mg	NOVARTIS PHARMA GMBH	GERMANY	8649	2016	01
MYCOPHENOLATUM	MYFORTIC 360 mg	GASTRORESISTANT TABLETS	360mg	NOVARTIS PHARMA GMBH	GERMANY	8650	2016	01
NIFEDIPINUM	NIFEDIPIN RETARD TERAPIA 20 mg	PROLONGED- RELEASE TABLETS	20mg	TERAPIA S.A.	ROMANIA	8675	2016	01
NIMESULIDUM	NIMESULID SLAVIA	TABLETS	100mg	SLAVIA PHARMA S.R.L.	ROMANIA	8534	2016	01

OMEPRAZOLUM	GASTRAPID 10 mg	GASTRORESISTANT CAPSULES	10mg	NATUR PRODUKT ZDROVIT SP. Z O.O.	POLAND	8592	2016	01
OMEPRAZOLUM	GASTRAPID 20 mg	GASTRORESISTANT CAPSULES	20mg	NATUR PRODUKT ZDROVIT SP. Z O.O.	POLAND	8593	2016	01
OXYTOCINUM	OXYTOCIN FERRING-LECIVA 1 UI	SOLUTION FOR INJECTION	1IU/ml	FERRING-LECIVA A.S.	THE CZECH REPUBLIC	8531	2016	01
OXYTOCINUM	OXYTOCIN FERRING-LECIVA 5 UI	SOLUTION FOR INJECTION	5IU/ml	FERRING-LECIVA A.S.	THE CZECH REPUBLIC	8532	2016	01
PACLITAXELUM	PACLITAXEL ACCORD 6 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	6mg/ml	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	8588	2016	01
PANTOPRAZOLUM	DICARBOCALM CONTROL 20 mg	GASTRORESISTANT TABLETS	20 mg	ZENTIVA S.A.	ROMANIA	8732	2016	01
PANTOPRAZOLUM	PANTOPRAZOL SUN 40 mg	POWDER FOR SOLUTION FOR INJECTION	40mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	HOLLAND	8472	2016	01
PARACETAMOLUM	DULSIFEB 24 mg/ml	ORAL SOLUTION	24 mg/ml	ACTAVIS GROUP PTC EHF.	ICELAND	8737	2016	01
PEMETREXEDUM	PEMETREXED STADA 25 mg	CONCENTRATE FOR SOLUTION FOR INFUSION	25mg/ml	STADA ARZNEIMITTEL AG	GERMANY	8738	2016	01
PENTOXIFYLLINUM	PENTOXI RETARD 400 mg	PROLONGED-RELEASE TABLETS	400mg	TERAPIA SA	ROMANIA	8743	2016	01
PERINDOPRILUM	TREZEN 4 mg	TABLETS	4mg	TERAPIA S.A.	ROMANIA	8758	2016	01
PERINDOPRILUM	TREZEN 8 mg	TABLETS	8mg	TERAPIA S.A.	ROMANIA	8759	2016	01
PLANTE	MUCOHELIX 8.25 mg/ml	SYRUP	8.25mg/ml	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	8771	2016	01
PLANTE	FRUNZA DE IEDERA BOEHRINGER INGELHEIM 8.25 mg/ml	SYRUP	8.25mg/ml	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	8772	2016	01
PRAVASTATINUM	PRAVASTATINA MYLAN	TABLETS	10mg	MYLAN S.A.S.	IRELAND	8768	2016	01

	10 mg							
PRAVASTATINUM	PRAVASTATINA MYLAN 20 mg	TABLETS	20mg	MYLAN S.A.S.	IRELAND	8769	2016	01
PRAVASTATINUM	PRAVASTATINA MYLAN 40 mg	TABLETS	40mg	MYLAN S.A.S.	IRELAND	8770	2016	01
PREDNISONUM	PREDNISON MCC 5 mg	TABLETS	5mg	MAGISTRA C&C S.R.L.	ROMANIA	8530	2016	01
PREGABALINUM	PREGABALINA TERAPIA 75 mg	CAPSULES	75mg	TERAPIA S.A.	ROMANIA	8608	2016	01
PREGABALINUM	PREGABALINA TERAPIA 150 mg	CAPSULES	150mg	TERAPIA S.A.	ROMANIA	8609	2016	01
PREGABALINUM	PREGABALINA TERAPIA 300 mg	CAPSULES	300mg	TERAPIA S.A.	ROMANIA	8610	2016	01
PROPAFENONUM	PROPAFENON SANDOZ 150 mg	FILM-COATED TABLETS	150mg	HEXAL AG	GERMANY	8643	2016	01
PROPRANOLOLUM	PROPRANOLOL 40 mg	TABLETS	40mg	SINTOFARM S.A.	ROMANIA	8748	2016	01
PROPRANOLOLUM	PROPRANOLOL 10 mg	TABLETS	10mg	SINTOFARM S.A.	ROMANIA	8747	2016	01
RABEPRAZOLUM	ZULBEX 10 mg	GASTRORESISTANT TABLETS	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8479	2016	01
RABEPRAZOLUM	ZULBEX 20 mg	GASTRORESISTANT TABLETS	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8480	2016	01
RACECADOTRILUM	IMOTEC 100 mg	CAPSULES	100mg	MCNEIL PRODUCTS LIMITED	GREAT BRITAIN	8736	2016	01
RAMIPRILUM	RAMIPRIL ATB 2.5 mg	TABLETS	2.5mg	ANTIBIOTICE S.A.	ROMANIA	8721	2016	01
RAMIPRILUM	RAMIPRIL ATB 5 mg	TABLETS	5mg	ANTIBIOTICE S.A.	ROMANIA	8722	2016	01
RAMIPRILUM	RAMIPRIL ATB 10 mg	TABLETS	10mg	ANTIBIOTICE S.A.	ROMANIA	8723	2016	01
RANITIDINUM	ARNETIN 50 mg/2 ml	SOLUTION FOR INJECTION	50mg/2ml	MEDOCHEMIE LTD.	CYPRUS	8671	2016	01
RASAGILINUM	RASAGILINA SANDOZ 1 mg	TABLETS	1mg	SANDOZ S.R.L.	ROMANIA	8579	2016	01
RASAGILINUM	RASAGILINA AUROBINDO 1 mg	TABLETS	1mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8582	2016	01

RASAGILINUM	RASAGILINA TORRENT 1 mg	TABLETS	1mg	TORRENT PHARMA S.R.L.	ROMANIA	8607	2016	01
RASAGILINUM	SAGILIA 1 mg	TABLETS	1mg	MEDOCHEMIE LTD	CYPRUS	8583	2016	01
REMIFENTANILUM	REMIFENTANIL HOSPIRA 1 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSIO N	1mg	HOSPIRA UK LIMITED	GREAT BRITAIN	8584	2016	01
REMIFENTANILUM	REMIFENTANIL HOSPIRA 2 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSIO N	2mg	HOSPIRA UK LIMITED	GREAT BRITAIN	8585	2016	01
REMIFENTANILUM	REMIFENTANIL HOSPIRA 5 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSIO N	5mg	HOSPIRA UK LIMITED	GREAT BRITAIN	8586	2016	01
REPAGLINIDUM	RENEOS 0.5 mg	TABLETS	0.5 mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	8505	2016	01
REPAGLINIDUM	RENEOS 1 mg	TABLETS	1 mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	8506	2016	01
REPAGLINIDUM	RENEOS 2 mg	TABLETS	2 mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	8507	2016	01
RIBAVIRINUM	RIBAVIRIN AUROBINDO 200 mg	CAPSULES	200mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8623	2016	01
RITONAVIRUM	RITONAVIR SANDOZ 100 mg	FILM-COATED TABLETS	100mg	SANDOZ S.R.L.	ROMANIA	8482	2016	01
RIVASTIGMINUM	RIVASTIGMINA TORRENT 13.3 mg/ 24 hours	TRANSDERMAL PATCH	13.3mg/24 hours	TORRENT PHARMA S.R.L.	ROMANIA	8578	2016	01
ROPIVACAINUM	NAROPIN 10 mg/ml	SOLUTION FOR INJECTION	10mg/ml	ASTRAZENECA AB	SWEDEN	8668	2016	01
ROSUVASTATINUM	ROSUVASTATINA TEVA 10 mg	FILM-COATED TABLETS	10mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8576	2016	01

ROSUVASTATINUM	ROSUVASTATINA TEVA 20 mg	FILM-COATED TABLETS	20mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8577	2016	01
SIMETHICONUM	ESPUMISAN 100 mg/ml	ORAL DROPS, EMULSION	100mg/ ml	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	8749	2016	01
SIMVASTATINUM	SIMVAHEXAL 10 mg	FILM-COATED TABLETS	10mg	HEXAL AG	GERMANY	8681	2016	01
SIMVASTATINUM	SIMVAHEXAL 30 mg	FILM-COATED TABLETS	30mg	HEXAL AG	GERMANY	8682	2016	01
SOLIFENACINUM SUCCINATE	ASOLFENA 5 mg	FILM-COATED TABLETS	5mg	KRKA D.D., NOVO MESTO	SLOVENIA	8687	2016	01
SOLIFENACINUM SUCCINATE	ASOLFENA 10 mg	FILM-COATED TABLETS	10mg	KRKA D.D., NOVO MESTO	SLOVENIA	8688	2016	01
STRONTIUM CLORIDE	METASTRON 37 MBq	SOLUTION FOR INJECTION	37 MBq/ml	GE HEALTHCARE LIMITED	GREAT BRITAIN	8755	2016	01
TACROLIMUSUM	TACROLIMUS SANDOZ 0.5 mg	CAPSULES	0.5mg	SANDOZ S.R.L.	ROMANIA	8570	2016	01
TACROLIMUSUM	TACROLIMUS SANDOZ 1 mg	CAPSULES	1mg	SANDOZ S.R.L.	ROMANIA	8571	2016	01
TACROLIMUSUM	TACROLIMUS SANDOZ 5 mg	CAPSULES	5mg	SANDOZ S.R.L.	ROMANIA	8572	2016	01
TAMSULOSINUM	TAMSULOSIN CIPLA 0.40 mg	PROLONGED- RELEASE CAPSULES	0.40mg	CIPLA UK LTD.	GREAT BRITAIN	8792	2016	01
TAPENTADOLUM	PALEXIA 50 mg	FILM-COATED TABLETS	50mg	GRUNENTHAL GMBH	GERMANY	8483	2016	01
TAPENTADOLUM	PALEXIA 75 mg	FILM-COATED TABLETS	75mg	GRUNENTHAL GMBH	GERMANY	8484	2016	01
TAPENTADOLUM	PALEXIA 100 mg	FILM-COATED TABLETS	100mg	GRUNENTHAL GMBH	GERMANY	8485	2016	01
TAPENTADOLUM	PALEXIA RETARD 25 mg	PROLONGED- RELEASE TABLETS	25mg	GRUNENTHAL GMBH	GERMANY	8486	2016	01
TAPENTADOLUM	PALEXIA RETARD 50 mg	PROLONGED- RELEASE TABLETS	50mg	GRUNENTHAL GMBH	GERMANY	8487	2016	01
TAPENTADOLUM	PALEXIA RETARD 100 mg	PROLONGED- RELEASE TABLETS	100mg	GRUNENTHAL GMBH	GERMANY	8488	2016	01

TAPENTADOLUM	PALEXIA RETARD 150 mg	PROLONGED- RELEASE TABLETS	150mg	GRUNENTHAL GMBH	GERMANY	8489	2016	01
TAPENTADOLUM	PALEXIA RETARD 200 mg	PROLONGED- RELEASE TABLETS	200mg	GRUNENTHAL GMBH	GERMANY	8490	2016	01
TAPENTADOLUM	PALEXIA RETARD 250 mg	PROLONGED- RELEASE TABLETS	250mg	GRUNENTHAL GMBH	GERMANY	8491	2016	01
TAPENTADOLUM	PALEXIA 4 mg/ml	ORAL SOLUTION	4mg/ml	GRUNENTHAL GMBH	GERMANY	8492	2016	01
TAPENTADOLUM	PALEXIA 20 mg/ml	ORAL SOLUTION	20mg/ml	GRUNENTHAL GMBH	GERMANY	8493	2016	01
TC 99 M - CELULE MARCATE CU EXAMETAZINUM	CERETEC 500 micrograms (see V09HA02)	KIT FOR RADIOPHARMACEU TICAL PREPARATION	500microg rams	GE HEALTHCARE LIMITED	GREAT BRITAIN	8754	2016	01
TC 99 M - CELULE MARCATE CU EXAMETAZINUM	CERETEC 500 micrograms (see V09AA01)	KIT FOR RADIOPHARMACEU TICAL PREPARATION	500microg rams	GE HEALTHCARE LIMITED	GREAT BRITAIN	8754	2016	01
TENOXICAMUM	TILCOTIL 20 mg	FILM-COATED TABLETS	20mg	MEDA PHARMA GMBH & CO. KG	GERMANY	8656	2016	01
TRAMADOLUM	TRAMADOL SR ZENTIVA 150 mg	PROLONGED- RELEASE TABLETS	150mg	ZENTIVA A.S.	SLOVAKIA	8764	2016	01
TRAMADOLUM	TRAMADOL SR ZENTIVA 100 mg	PROLONGED- RELEASE TABLETS	100mg	ZENTIVA A.S.	SLOVAKIA	8763	2016	01
TRAMADOLUM	MABRON 50 mg	CAPSULES	50mg	MEDOCHEMIE LTD.	CYPRUS	8728	2016	01
TRAVOPROSTUM	TRAELEB 40 micrograms/ml	EYE DROPS, SOLUTION	40microgr ams/ml	ALFRED E. TIEFENBACHE GMBH & CO.KG	GERMANY	8667	2016	01
TRIPTORELINUM	DIPHERELINE 22.5 mg	PROLONGED- RELEASE POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	22.5mg	IPSEN PHARMA	FRANCE	8689	2016	01
TROPICAMIDUM	MYDRIACYL 5 mg/ml	EYE DROPS, SOLUTION	5mg/ml	ALCON COUVREUR N.V.	BELGIUM	8674	2016	01
VALSARTANUM	VALSARGAMMA 40 mg	FILM-COATED TABLETS	40mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	8500	2016	01

VALSARTANUM	VALSARGAMMA 80 mg	FILM-COATED TABLETS	80mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	8501	2016	01
VALSARTANUM	VALSARGAMMA 160 mg	FILM-COATED TABLETS	160mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	8502	2016	01
VALSARTANUM	VALSARGAMMA 320 mg	FILM-COATED TABLETS	320mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	8503	2016	01
VANCOMYCINUM	VANCOMICINA KABI 500 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	500mg	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	8512	2016	01
VANCOMYCINUM	VANCOMICINA KABI 1000 mg	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	1000mg	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	8513	2016	01
VIRUS TBE (VIRUSUL ENCEFALITEI TRANSMIS DE CAPUSE)	FSME-IMMUN 0.5 ml	SUSPENSION FOR INJECTION IN PRE- FILLED SYRINGE	0.5ml	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8686	2016	01
VIRUS TBE(VIRUSUL ENCEFALITEI TRANS.DE CAPSUSE),	FSME-IMMUN 0.25 ml JUNIOR	SUSPENSION FOR INJECTION IN PRE- FILLED SYRINGE	0.25ml	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8685	2016	01
XYLOMETAZOLINUM	OLYNTH HA 1 mg/ml	NASAL SPRAY, SOLUTION	1mg/ml	MCNEIL PRODUCTS LIMITED C/O JOHNSON&JOHNSON	GREAT BRITAIN	8558	2016	01
ZOPICLONUM	IMOVANE 7.5 mg	FILM-COATED TABLETS	7.5mg	SANOFI - AVENTIS FRANCE	FRANCE	8632	2016	01
ZOPICLONUM	SONLAX 7.5 mg	FILM-COAED TABLETS	7.5 mg	AS GRINDEKS	LATVIA	8761	2016	01

Medicinal products authorised through centralised procedure by the EMA, notified for marketing in Romania during the 1st quarter of 2016

INN	Invented name	Pharmaceutical form	Strength	MAH	Country	MA number		
ASPARAGINAZUM	SPECTRILA 10000 IU	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	10000IU	MEDAC GESELLSCHAFT FÜR KLINISCHE SPEZIALPRÄPARATE	GERMANY	1072	2016	01
OSIMERTINIB	TAGRISSE 40 mg	FILM-COATED TABLETS	40mg	ASTRA ZENECA AB	SWEDEN	1086	2016	01
OSIMERTINIB	TAGRISSE 80 mg	FILM-COATED TABLETS	80mg	ASTRA ZENECA AB	SWEDEN	1086	2016	01
PEMETREXEDUM	ARMISARTE 25 mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	25mg/ ml	ACTAVIS GROUP PTC EHF.	ICELAND	1063	2016	01