26 October 2017
EMA/663554/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): clodronic acid

Procedure No.: PSUSA/00000804/201702

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Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ACIDO CLODRONICO EG 100 mg/3,3 ml soluzione iniettabile	not available	035014012	EG S.P.A.	IT
Bonefos 400 mg tvrdé kapsuly	not available	44/0093/89-S	BAYER OY	SK
Bonefos 400 mg tvrdé kapsuly	not available	44/0093/89-S	BAYER OY	SK
Bonefos 400 mg cápsulas	not available	60.547	BAYER HISPANIA SL	ES
Bonefos 400 mg cápsulas	not available	60.547	BAYER HISPANIA SL	ES
Bonefos 400 mg capsules	not available	PL 00010/0521	BAYER PLC	UK
Bonefos 400 mg capsules	not available	PL 00010/0521	BAYER PLC	UK
Bonefos 400 mg capsules.	not available	MA513/04001	BAYER PLC	MT
Bonefos 400 mg capsules.	not available	MA513/04001	BAYER PLC	MT
Bonefos 400 mg cietās kapsulas	not available	95-0246	BAYER AG	LV
Bonefos 400 mg cietās kapsulas	not available	95-0246	BAYER AG	LV
Bonefos 400 mg kapseli, kova	not available	8962	BAYER OY	FI
Bonefos 400 mg kapseli, kova	not available	8962	BAYER OY	FI
Bonefos 400 mg kapsule, tvrde	not available	HR-H-858593343-01	BAYER DOO	HR

Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Bonefos 400 mg kapsule, tvrde	not available	HR-H-858593343-01	BAYER DOO	HR
BONEFOS 400 mg Tvrdé tobolky	not available	44/093/89-S/C	BAYER OY	CZ
BONEFOS 400 mg Tvrdé tobolky	not available	44/093/89-S/C	BAYER OY	CZ
Bonefos 400 mg, capsules	not available	RVG 13881	BAYER BV	NL
Bonefos 400 mg, capsules	not available	RVG 13881	BAYER BV	NL
BONEFOS 60 mg/ml, concentraat voor oplossing voor infusie	not available	BE166311	BAYER SA NV	BE
BONEFOS 60 mg/ml, concentraat voor oplossing voor infusie	not available	BE166311	BAYER SA NV	BE
BONEFOS 60 mg/ml, solution à diluer pour perfusion	not available	BE166311	BAYER SA NV	BE
BONEFOS 60 mg/ml, solution à diluer pour perfusion	not available	BE166311	BAYER SA NV	BE
Bonefos 800 mg comprimate filmate	not available	8458/2015/01	BAYER OY	RO

Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Bonefos 800 mg comprimate filmate	not available	8458/2015/01	BAYER OY	RO
Bonefos 800 mg comprimidos revestidos por película	not available	3256286	BAYER PORTUGAL LDA	PT
Bonefos 800 mg comprimidos revestidos por película	not available	3256286	BAYER PORTUGAL LDA	PT
Bonefos 800 mg film-coated tablets	not available	PA 1410/2/1	BAYER LTD	IE
Bonefos 800 mg film-coated tablets	not available	PA 1410/2/1	BAYER LTD	IE
Bonefos 800 mg filmdragerade tabletter	not available	11659	BAYER AB	SE
Bonefos 800 mg filmdragerade tabletter	not available	11659	BAYER AB	SE
Bonefos 800 mg filmom obalené tablety	not available	87/0366/00-S	BAYER OY	SK
Bonefos 800 mg filmom obalené tablety	not available	87/0366/00-S	BAYER OY	SK
Bonefos 800 mg filmsko obložene tablete	not available	H/03/00296/001	BAYER OY	SI

Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Bonefos 800 mg filmsko obložene tablete	not available	H/03/00296/001	BAYER OY	SI
BONEFOS 800 mg Potahované tablety	not available	44/291/99-C	BAYER OY	CZ
BONEFOS 800 mg Potahované tablety	not available	44/291/99-C	BAYER OY	CZ
Bonefos 800 mg tablets	not available	PL 00010/0522	BAYER PLC	UK
Bonefos 800 mg tablets	not available	PL 00010/0522	BAYER PLC	UK
Bonefos 800 mg tablett, filmdrasjert.	not available	95/2772	BAYER AB	NO
Bonefos 800 mg tablett, filmdrasjert.	not available	95/2772	BAYER AB	NO
Bonefos 800 mg tabletta	not available	OGYI-T-2027/04	BAYER OY	HU
Bonefos 800 mg tabletta	not available	OGYI-T-2027/04	BAYER OY	HU
Bonefos 800 mg tabletti, kalvopäällysteinen	not available	12157	BAYER OY	FI
Bonefos 800 mg tabletti, kalvopäällysteinen	not available	12157	BAYER OY	FI
BONEFOS 800 mg, comprimés pelliculés	not available	BE182244	BAYER SA NV	BE
BONEFOS 800 mg, comprimés pelliculés	not available	BE182244	BAYER SA NV	BE

Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
BONEFOS 800 mg, comprimés pelliculés	not available	0442/11101296	BAYER SA NV	LU
BONEFOS 800 mg, comprimés pelliculés	not available	0442/11101296	BAYER SA NV	LU
BONEFOS 800 mg, filmomhulde tabletten	not available	BE182244	BAYER SA NV	BE
BONEFOS 800 mg, filmomhulde tabletten	not available	BE182244	BAYER SA NV	BE
Bonefos 800 mg, filmomhulde tabletten	not available	RVG 20245	BAYER BV	NL
Bonefos 800 mg, filmomhulde tabletten	not available	RVG 20245	BAYER BV	NL
Bonefos, 400 mg, kapsułki twarde	not available	R/0298	BAYER PHARMA AG	PL
Bonefos, 400 mg, kapsułki twarde	not available	R/0298	BAYER PHARMA AG	PL
Bonefos, filmovertrukne tabletter	not available	14628	BAYER AB	DK
Bonefos, filmovertrukne tabletter	not available	14628	BAYER AB	DK
Bonefos® 400 mg Hartkapsel	not available	19695.00.00	BAYER VITAL GMBH	DE

Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Bonefos® 400 mg Hartkapsel	not available	19695.00.00	BAYER VITAL GMBH	DE
BONEFOS® 60 mg/ml Konzentrat zu Herstellung einer Infusionslösung	not available	BE166311	BAYER SA NV	BE
BONEFOS® 60 mg/ml Konzentrat zu Herstellung einer Infusionslösung	not available	BE166311	BAYER SA NV	BE
BONEFOS® 800 mg, Filmtabletten	not available	BE182244	BAYER SA NV	BE
BONEFOS® 800 mg, Filmtabletten	not available	BE182244	BAYER SA NV	BE
BONEFOS® 800 mg, Filmtabletten	not available	0442/11101296	BAYER SA NV	LU
BONEFOS® 800 mg, Filmtabletten	not available	0442/11101296	BAYER SA NV	LU
Bonefos® Filmtabletten 800 mg	not available	19695.01.02	BAYER VITAL GMBH	DE
Bonefos® Filmtabletten 800 mg	not available	19695.01.02	BAYER VITAL GMBH	DE
CLASTEON 300 mg/10 ml concentrato per soluzione per infusione	not available	026372045	ABIOGEN PHARMA S.P.A.	IT

Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
CLASTEON 300 mg/10 ml concentrato per soluzione per infusione	not available	026372033	ABIOGEN PHARMA S.P.A.	IT
CLASTEON 400 mg capsule rigide	not available	026372058	ABIOGEN PHARMA S.P.A.	IT
CLASTEON 400mg capsules	not available	S00700	BEACON PHARMACEUTICALS LIMITED	CY
CLASTEON® 800mg film-coated tablets	UK/H/3419/001	PL 18157/0225	BEACON PHARMACEUTICALS LIMITED	UK
CLODEOSTEN 100 mg/3,3 ml soluzione iniettabile	not available	035109014	S.F. GROUP SRL	IT
CLODRON 300 mg/10ml concentrato per soluzione per infusione	not available	034721047	FIDIA FARMACEUTICI S.P.A	IT
CLODRON 300 mg/10ml concentrato per soluzione per infusione	not available	034721035	FIDIA FARMACEUTICI S.P.A	IT
Clodron 400 - 1 A Pharma	2147286	47286.00.00	1 A PHARMA GMBH	DE
CLODRON 400 mg capsule rigide	not available	034721050	FIDIA FARMACEUTICI S.P.A	IT
Clodron 400 mg HEXAL® Filmtabletten	not available	47282.00.00	HEXAL AG	DE
Clodron 800 - 1 A Pharma	2147287	47286.01.00	1 A PHARMA GMBH	DE

Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Clodron 800 mg HEXAL® Filmtabletten	not available	47282.01.00	HEXAL AG	DE
CLODRONATO ABC 100 mg/3,3 ml soluzione iniettabile	not available	035129016	ABC FARMACEUTICI S.P.A.	IT
CLODRONATO ABC 100 mg/3,3 ml soluzione iniettabile	not available	035129028	ABC FARMACEUTICI S.P.A.	IT
CLODRONATO ABC 300 mg/10 ml soluzione per infusione endovenosa	not available	035129030	ABC FARMACEUTICI S.P.A.	IT
CLODY 300 mg/10 ml concentrato per soluzione per infusione	not available	034294037	PROMEDICA S.R.L.	IT
DIFOSFONAL 300 mg/10 ml concentrato per soluzione per infusione	not available	026510038	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
DIFOSFONAL 300 mg/10 ml concentrato per soluzione per infusione	not available	026510040	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
DIFOSFONAL 400 mg capsule rigide	not available	026510053	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
Lodronat 520	not available	87/139/99-C	RIEMSER PHARMA GMBH	CZ

Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Lodronat 520 mg	not available	1-20266	RIEMSER PHARMA GMBH	AT
Loron 520 520 mg, film-coated tablets	not available	PL 42336/0002	RIEMSER PHARMA GMBH	UK
LYTOS 520 mg	not available	3400934042416	RIEMSER PHARMA GMBH	FR
MOTICLOD 100 mg/3,3 ml soluzione iniettabile	not available	035044027	LAB. IT. BIOCHIM. FARM.CO LISAPHARMA S.P.A.	IT
MOTICLOD 100 mg/3,3 ml soluzione iniettabile	not available	035044015	LAB. IT. BIOCHIM. FARM.CO LISAPHARMA S.P.A.	IT
MOTICLOD 300 mg/10 ml soluzione per infusione	not available	035044039	LAB. IT. BIOCHIM. FARM.CO LISAPHARMA S.P.A.	IT
Neogrand 800 mg filmtabletta	not available	OGYI-T-22548/01	ONCO-EUROPE LTD.	HU
Neogrand 800 mg filmtabletta	not available	OGYI-T-22548/02	ONCO-EUROPE LTD.	HU
Neogrand 800 mg filmtabletta	not available	OGYI-T-22548/03	ONCO-EUROPE LTD.	HU
Neogrand 800 mg filmtabletta	not available	OGYI-T-22548/04	ONCO-EUROPE LTD.	HU
NIKLOD 300 mg/10 ml concentrato per soluzione per infusione	not available	034292033	I.B.N. SAVIO S.R.L.	IT

Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
NIKLOD 300 mg/10 ml concentrato per soluzione per infusione	not available	034292033	I.B.N. SAVIO S.R.L.	IT
Ostac 520	not available	RVG 18051	RIEMSER PHARMA GMBH	NL
Ostac 520 mg	not available	8856.00.02	RIEMSER PHARMA GMBH	DE
Ostac 520 mg comprimidos revestidos	not available	2394088	RIEMSER PHARMA GMBH	PT
Ostac 520 mg comprimidos revestidos	not available	2394187	RIEMSER PHARMA GMBH	PT
OSTEONORM 100 mg/ 3,3 ml soluzione iniettabile	not available	034293023	I.B.N. SAVIO S.R.L.	IT
OSTEONORM 100 mg/ 3,3 ml soluzione iniettabile	not available	034293011	I.B.N. SAVIO S.R.L.	IT
OSTEONORM 100 mg/ 3,3 ml soluzione iniettabile	not available	034293023	I.B.N. SAVIO S.R.L.	IT
OSTEONORM 100 mg/ 3,3 ml soluzione iniettabile	not available	034293011	I.B.N. SAVIO S.R.L.	IT
SINDRONAT	not available	87/0340/03-S	ACTAVIS SRL	SK
SINDRONAT 300 MG/5 ML, CONCENTRAT PENTRU SOLUŢIE PERFUZABILĂ	not available	2261/2016/01	ACTAVIS SRL	RO

Product name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
SINDRONAT, 400 mg, kapsulki twarde	9535	9535	ACTAVIS GROUP PTC EHF.	PL
TRAXOVICAL “100 mg/ 3,3 ml soluzione iniettabile”	not available	036219018	SAVIO PHARMA ITALIA SRL	IT
TRAXOVICAL “100 mg/ 3,3 ml soluzione iniettabile”	not available	036219018	SAVIO PHARMA ITALIA SRL	IT