



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 May 2018
EMA/302974/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): dexibuprofen

Procedure No.: PSUSA/00000996/201708



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
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	4162780	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	3921186	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	3921285	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	3921483	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	3921681	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	3921780	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	3921384	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	4162582	JABA RECORDATI, S.A.	PT
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	3921582	JABA RECORDATI, S.A.	PT
Tradil 400 mg, filmdragerad tablett	AT/H/0111/003	16318	NORDIC DRUGS AB	SE
Seractiv, filmovertrukne tabletter	AT/H/0111/003	31504	NORDIC DRUGS AB	DK
Dexibuprofen „Gebro“ 400 mg - Filmdragerad tablett	AT/H/0111/003	1-23572	GEBRO PHARMA GMBH	AT
Dolomagon 400 mg - Filmdragerad tablett	AT/H/0111/003	49603.02.00	GEBRO PHARMA GMBH	DE
Seractil 400 mg film-coated Tablets	AT/H/0111/003	PL 04536/0007	GEBRO PHARMA GMBH	UK
SERACTIL 400 mg comprimidos recubiertos con película	AT/H/0111/003	63.574	LABORATORIOS GEBRO PHARMA, S.A.	ES
Seractil 400 mg comprimidos revestidos por película	AT/H/111/03	3333481	JABA RECORDATI, S.A.	PT

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
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765139	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765141	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765154	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765166	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765178	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 400 mg compresse rivestite con film	AT/H/0111/003	034765180	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 400 mg επικαλυμμένα με λεπτό υμένιο δισκία	AT/H/0111/003	60178/04-07-2017	GALENICA SA	GR
Atriscal 200 mg Filmtabletten	not available	1-31858	GEBRO PHARMA GMBH	AT
Atriscal 300 mg - Filmtabletten	not available	1-31859	GEBRO PHARMA GMBH	AT
Atriscal 400 mg - Filmtabletten	not available	1-31860	GEBRO PHARMA GMBH	AT
Seractil 200 mg - Filmtabletten	not available	1-20001	GEBRO PHARMA GMBH	AT
Seractil akut 400 mg Pulver zur Herstellung einer Suspension zum Einnehmen	AT/H/0111/006	1-27876	GEBRO PHARMA GMBH	AT
Seractil 400 mg polvere per sospensione orale	AT/H/0111/006	034765216	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 400 mg polvere per sospensione orale	AT/H/0111/006	034765279	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 400 mg polvere per sospensione orale	AT/H/0111/006	034765228	THERABEL GIENNE 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
Seractil 400 mg polvere per sospensione orale	AT/H/0111/006	034765230	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 300 mg - Filmtabletten	not available	1-20002	GEBRO PHARMA GMBH	AT
Deltaran® 200 mg Filmtabletten	AT/H/0112/001	49606.00.00	PHARMORE GMBH	DE
Movone 200 mg - Filmtabletten	AT/H/0112/001	1-23573	GEBRO PHARMA GMBH	AT
Deltaran® 400 mg Filmtabletten	AT/H/0112/003	49606.02.00	PHARMORE GMBH	DE
Movone 400 mg - Filmtabletten	AT/H/0112/003	1-23575	GEBRO PHARMA GMBH	AT
ATRISCAL 400 mg comprimidos recubiertos con película	AT/H/0112/003	63.606	LABORATORIOS GEBRO PHARMA, S.A.	ES
Seractil Dolo 200 mg filmtabletta	not available	OGYI-T-7307/01	GEBRO PHARMA GMBH	HU
Seractil 400 mg filmtabletta	not available	OGYI-T-7307/09	GEBRO PHARMA GMBH	HU
Seractil 400 mg filmtabletta	not available	OGYI-T-7307/10	GEBRO PHARMA GMBH	HU
Seractil 400 mg filmtabletta	not available	OGYI-T-7307/11	GEBRO PHARMA GMBH	HU
Seractil Dolo 200 mg filmtabletta	not available	OGYI-T-7307/02	GEBRO PHARMA GMBH	HU
Seractil Dolo 200 mg filmtabletta	not available	OGYI-T-7307/03	GEBRO PHARMA GMBH	HU
Seractil Dolo 300 mg filmtabletta	not available	OGYI-T-7307/05	GEBRO PHARMA GMBH	HU
Seractil Dolo 300 mg filmtabletta	not available	OGYI-T-7307/06	GEBRO PHARMA GMBH	HU
Seractil Dolo 300 mg filmtabletta	not available	OGYI-T-7307/07	GEBRO PHARMA GMBH	HU
Seractil Dolo 300 mg filmtabletta	not available	OGYI-T-7307/08	GEBRO PHARMA GMBH	HU
Seractil Dolo 200 mg filmtabletta	not available	OGYI-T-7307/04	GEBRO PHARMA GMBH	HU
Seractil Dolo 300 mg filmtabletta	not available	OGYI-T-7307/13	GEBRO PHARMA GMBH	HU
Seractil 400 mg filmtabletta	not available	OGYI-T-7307/12	GEBRO PHARMA GMBH	HU
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	3920683	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	3920584	JABA RECORDATI, S.A.	PT

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
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	3333283	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	3920782	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	3920881	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	3920980	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	3921087	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	4162681	JABA RECORDATI, S.A.	PT
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	4162483	JABA RECORDATI, S.A.	PT
Tradil 300 mg filmdragerad tablett	AT/H/0111/002	16317	NORDIC DRUGS AB	SE
Seractiv, fillovertrukne tabletter	AT/H/0111/002	31503	NORDIC DRUGS AB	DK
Dexibuprofen „Gebro“ 300 mg - Filmtabletten	AT/H/0111/002	1-23571	GEBRO PHARMA GMBH	AT
Dolomagon 300 mg Filmtabletten	AT/H/0111/002	49603.01.00	GEBRO PHARMA GMBH	DE
Seractil 300 mg film-coated tablets	AT/H/0111/002	PL 04536/0006	GEBRO PHARMA GMBH	UK
Seractil 300 mg comprimidos revestidos por película	AT/H/111/02	3333382	JABA RECORDATI, S.A.	PT
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765077	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765089	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765091	THERABEL GIENNE 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
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765103	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765115	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 300 mg compresse rivestite con film	AT/H/0111/002	034765127	THERABEL GIENNE PHARMA S.P.A.	IT
Seractil 300 mg επικαλυμμένα με λεπτό υμένιο δισκία	AT/H/0111/002	60178/04-07-2017	GALENICA SA	GR
Seractil, 200 mg, tabletki powlekane	not available	8441	BIOFARM SP. Z O.O.	PL
Seractil, 400 mg, tabletki powlekane	not available	8443	BIOFARM SP. Z O.O.	PL
Seractil akut 300 mg Pulver zur Herstellung einer Suspension zum Einnehmen	AT/H/0111/005	1-27875	GEBRO PHARMA GMBH	AT
Seractil 300 mg polvere per sospensione orale	AT/H/0111/005	034765204	THERABEL GIENNE PHARMA S.P.A.	IT
Deltaran® 300 mg Filmtabletten	AT/H/0112/002	49606.01.00	PHARMORE GMBH	DE
Movone 300 mg - Filmtabletten	AT/H/0112/002	1-23574	GEBRO PHARMA GMBH	AT
ATRISCAL 300 mg comprimidos recubiertos con película	AT/H/0112/002	63.607	LABORATORIOS GEBRO PHARMA, S.A.	ES
Seractil forte 400 mg - Filmtabletten	not available	1-22547	GEBRO PHARMA GMBH	AT
FENEXTRA “400 mg Compresse rivestite con film”	not available	035512045	BRUNO FARMACEUTICI	IT
FENEXTRA “200 mg Granulato per sospensione orale”	not available	035512108	BRUNO FARMACEUTICI	IT
FENEXTRA “300 mg Granulato per sospensione orale”	not available	035512072	BRUNO FARMACEUTICI	IT
FENEXTRA “400 mg Granulato per sospensione orale”	not available	035512084	BRUNO FARMACEUTICI	IT

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Actifen 200 mg - Filmtabletten	not available	1-21533	GEBRO PHARMA GMBH	AT
Eu-Med 200 mg Schmerztabletten	not available	1-21535	GEBRO PHARMA GMBH	AT