



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 January 2024  
EMA/95353/2024  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): gadoteric acid (IV and intravascular formulations)

Procedure No. PSUSA/00001506/202304



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
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	137430	GE HEALTHCARE HANDELS GMBH	AT
Clariscan 0,5 mmol/ml Injektionslösung in einer Fertigspritze	SE/H/1562/002	137431	GE HEALTHCARE HANDELS GMBH	AT
Cyclolux 0,5 mmol/ml Injektionslösung	DE/H/4015/002	136612	SANOCHEMIA PHARMAZEUTIKA GMBH	AT
Cyclolux 0,5 mmol/ml Injektionslösung im Einzeldosisbehältnis	DE/H/4015/001	136613	SANOCHEMIA PHARMAZEUTIKA GMBH	AT
Dotagraf 0,5 mmol/ml Injektionslösung	DE/H/3944/002	136455	BAYER AUSTRIA GMBH	AT
Dotarem - Injektionslösung	not available	1-21996	GUERBET	AT
Acide gadotérique Guerbet 0,5 mmol/ml Injektionslösung in Durchstechflaschen	NL/H/2028/001	BE530817	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml Injektionslösung in Durchstechflaschen	NL/H/2028/001	BE530800	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml Injektionslösung in Durchstechflaschen	NL/H/2028/001	BE530835	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml Injektionslösung in Durchstechflaschen	NL/H/2028/001	BE530853	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml Injektionslösung in Durchstechflaschen	NL/H/2028/001	BE530862	GUERBET	BE
Acide gadotérique	NL/H/2028/002	BE530871	GUERBET	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
Guerbet 0,5 mmol/ml Injektionslösung in Durchstechflaschen (für Mehrfachentnahme)				
Acide gadotérique Guerbet 0,5 mmol/ml Injektionslösung in Durchstechflaschen (für Mehrfachentnahme)	NL/H/2028/002	BE530880	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml Injektionslösung in Fertigspritzen	NL/H/2028/003	BE530773	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml Injektionslösung in Fertigspritzen	NL/H/2028/003	BE530782	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml Injektionslösung in Fertigspritzen	NL/H/2028/003	BE530791	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml solution injectable en flacon (pour usage multiple)	NL/H/2028/002	BE530871	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml solution injectable en flacon (pour usage multiple)	NL/H/2028/002	BE530880	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml solution injectable en flacons	NL/H/2028/001	BE530800	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml solution injectable en flacons	NL/H/2028/001	BE530817	GUERBET	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
Acide gadotérique Guerbet 0,5 mmol/ml solution injectable en flacons	NL/H/2028/001	BE530835	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml solution injectable en flacons	NL/H/2028/001	BE530853	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml solution injectable en flacons	NL/H/2028/001	BE530862	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, oplossing voor injectie in injectieflacons	NL/H/2028/001	BE530817	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, oplossing voor injectie in injectieflacons	NL/H/2028/001	BE530800	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, oplossing voor injectie in injectieflacons	NL/H/2028/001	BE530835	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, oplossing voor injectie in injectieflacons	NL/H/2028/001	BE530853	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, oplossing voor injectie in injectieflacons	NL/H/2028/001	BE530862	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, oplossing voor injectie in injectieflacons (voor meervoudig gebruik).	NL/H/2028/002	BE530871	GUERBET	BE
Acide gadotérique	NL/H/2028/002	BE530880	GUERBET	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
Guerbet 0,5 mmol/ml, oplossing voor injectie in injectieflacons (voor meervoudig gebruik).				
Acide gadotérique Guerbet 0,5 mmol/ml, oplossing voor injectie in voorgevulde spuit.	NL/H/2028/003	BE530773	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, oplossing voor injectie in voorgevulde spuit.	NL/H/2028/003	BE530782	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, oplossing voor injectie in voorgevulde spuit.	NL/H/2028/003	BE530791	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, solution injectable en seringue préremplie	NL/H/2028/003	BE530773	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, solution injectable en seringue préremplie	NL/H/2028/003	BE530782	GUERBET	BE
Acide gadotérique Guerbet 0,5 mmol/ml, solution injectable en seringue préremplie	NL/H/2028/003	BE530791	GUERBET	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517786	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517786	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517795	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517795	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517804	GE HEALTHCARE AS	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
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517804	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517822	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517813	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517822	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517813	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517831	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517831	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517840	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517840	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517857	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie	SE/H/1562/001	BE517857	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie in een voorgevulde spuit	SE/H/1562/002	BE517866	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie in een voorgevulde spuit	SE/H/1562/002	BE517866	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie in een voorgevulde spuit	SE/H/1562/002	BE517875	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie in een voorgevulde spuit	SE/H/1562/002	BE517884	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml oplossing voor injectie in een voorgevulde spuit	SE/H/1562/002	BE517875	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ ml	SE/H/1562/002	BE517884	GE HEALTHCARE AS	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
oplossing voor injectie in een voorgevulde spuit				
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517786	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517786	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517795	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517804	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517795	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517804	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517813	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517813	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517822	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517822	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517831	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517831	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517840	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517840	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517857	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	BE517857	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung in einer Fertigspritze	SE/H/1562/002	BE517866	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml	SE/H/1562/002	BE517866	GE HEALTHCARE AS	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
Injektionslösung in einer Fertigspritze				
Clariscan 0,5 mmol/ml Injektionslösung in einer Fertigspritze	SE/H/1562/002	BE517875	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung in einer Fertigspritze	SE/H/1562/002	BE517875	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung in einer Fertigspritze	SE/H/1562/002	BE517884	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml Injektionslösung in einer Fertigspritze	SE/H/1562/002	BE517884	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517786	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517786	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517795	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517795	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517804	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517804	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517813	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517813	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517822	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517822	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517831	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517831	GE HEALTHCARE AS	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
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517840	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517840	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517857	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	BE517857	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable en seringue préremplie	SE/H/1562/002	BE517866	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable en seringue préremplie	SE/H/1562/002	BE517866	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable en seringue préremplie	SE/H/1562/002	BE517875	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable en seringue préremplie	SE/H/1562/002	BE517875	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable en seringue préremplie	SE/H/1562/002	BE517884	GE HEALTHCARE AS	BE
Clariscan 0,5 mmol/ml, solution injectable en seringue préremplie	SE/H/1562/002	BE517884	GE HEALTHCARE AS	BE
Dotagraph 0,5 mmol/ml Injektionslösung (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475315	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml Injektionslösung (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475333	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml Injektionslösung (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475324	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml Injektionslösung (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475315	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
Dotagraph 0,5 mmol/ml Injektionslösung (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475333	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml Injektionslösung (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475324	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml Injektionslösung (60 ml/100 ml)	DE/H/3944/002	BE475342	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml Injektionslösung (60 ml/100 ml)	DE/H/3944/002	BE475351	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml oplossing voor injectie (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475315	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml oplossing voor injectie (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475324	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml oplossing voor injectie (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475333	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml oplossing voor injectie (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475315	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml oplossing voor injectie (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475324	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml oplossing voor injectie (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475333	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml oplossing voor injectie (60 ml/100 ml)	DE/H/3944/002	BE475342	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml oplossing voor injectie (60 ml/100 ml)	DE/H/3944/002	BE475351	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml solution injectable (10	DE/H/3944/001	BE475315	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
ml/15 ml/20 ml)				
Dotagraph 0,5 mmol/ml solution injectable (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475324	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml solution injectable (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475333	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml solution injectable (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475315	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml solution injectable (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475324	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml solution injectable (10 ml/15 ml/20 ml)	DE/H/3944/001	BE475333	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml solution injectable (60 ml/100 ml)	DE/H/3944/002	BE475342	BAYER SA NV	BE
Dotagraph 0,5 mmol/ml solution injectable (60 ml/100 ml)	DE/H/3944/002	BE475351	BAYER SA NV	BE
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE184615	GUERBET	BE
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE149362	GUERBET	BE
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE149371	GUERBET	BE
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE149353	GUERBET	BE
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE 226055	GUERBET	BE
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE254992	GUERBET	BE
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE169547	GUERBET	BE
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE169531	GUERBET	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
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE553733	GUERBET	BE
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE553724	GUERBET	BE
Dotarem 0,5 mmol/ml, Injektionslösung	not available	BE553715	GUERBET	BE
Dotarem 0,5 mmol/mL, oplossing voor injectie.	not available	BE184615	GUERBET	BE
Dotarem 0,5 mmol/mL, oplossing voor injectie.	not available	BE 149362	GUERBET	BE
Dotarem 0,5 mmol/mL, oplossing voor injectie.	not available	BE149371	GUERBET	BE
Dotarem 0,5 mmol/mL, oplossing voor injectie.	not available	BE149353	GUERBET	BE
Dotarem 0,5 mmol/mL, oplossing voor injectie.	not available	BE 226055	GUERBET	BE
Dotarem 0,5 mmol/mL, oplossing voor injectie.	not available	BE254992	GUERBET	BE
Dotarem 0,5 mmol/mL, oplossing voor injectie.	not available	BE169547	GUERBET	BE
Dotarem 0,5 mmol/mL, oplossing voor injectie.	not available	BE 169531	GUERBET	BE
Dotarem 0,5 mmol/ml, oplossing voor injectie.	not available	BE553733	GUERBET	BE
Dotarem 0,5 mmol/ml, oplossing voor injectie.	not available	BE553724	GUERBET	BE
Dotarem 0,5 mmol/ml, oplossing voor injectie.	not available	BE553715	GUERBET	BE
Dotarem 0,5 mmol/mL, solution injectable	not available	BE184615	GUERBET	BE
Dotarem 0,5 mmol/mL, solution injectable	not available	BE149362	GUERBET	BE
Dotarem 0,5 mmol/mL, solution injectable	not available	BE149371	GUERBET	BE
Dotarem 0,5 mmol/mL, solution injectable	not available	BE149353	GUERBET	BE
Dotarem 0,5 mmol/mL, solution injectable	not available	BE226055	GUERBET	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
Dotarem 0,5 mmol/mL, solution injectable	not available	BE254992	GUERBET	BE
Dotarem 0,5 mmol/mL, solution injectable	not available	BE 169547	GUERBET	BE
Dotarem 0,5 mmol/mL, solution injectable	not available	BE169531	GUERBET	BE
Dotarem 0,5 mmol/ml, solution injectable	not available	BE553733	GUERBET	BE
Dotarem 0,5 mmol/ml, solution injectable	not available	BE553724	GUERBET	BE
Dotarem 0,5 mmol/ml, solution injectable	not available	BE553715	GUERBET	BE
Macrocyclolux 0,5 mmol/ml oplossing voor injectie	DE/H/4015/002	BE660853	SANOCHEMIA PHARMAZEUTIKA GMBH	BE
Macrocyclolux 0,5 mmol/ml oplossing voor injectie	DE/H/4015/002	BE660854	SANOCHEMIA PHARMAZEUTIKA GMBH	BE
Macrocyclolux 0,5 mmol/ml oplossing voor injectie	DE/H/4015/001	BE660850	SANOCHEMIA PHARMAZEUTIKA GMBH	BE
Macrocyclolux 0,5 mmol/ml oplossing voor injectie	DE/H/4015/001	BE660851	SANOCHEMIA PHARMAZEUTIKA GMBH	BE
Macrocyclolux 0,5 mmol/ml oplossing voor injectie	DE/H/4015/001	BE660852	SANOCHEMIA PHARMAZEUTIKA GMBH	BE
Дотаграф 0,5 mmol/ml инъекционен разтвор	DE/H/3944/001	20160389	BAYER AG	BG
Дотаграф 0,5 mmol/ml инъекционен разтвор	DE/H/3944/002	20160390	BAYER AG	BG
Дотаграф 0,5 mmol/ml инъекционен разтвор	DE/H/3944/001	20160389	BAYER AG	BG
Кларискан 0,5 mmol/ml инъекционен разтвор	SE/H/1562/001	20180016	GE HEALTHCARE AS	BG
Кларискан 0,5 mmol/ml инъекционен разтвор в предварително	SE/H/1562/002	20180015	GE HEALTHCARE AS	BG

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
напълнена спринцовка				
Clariscan 0,5 mmol/ mL ενέσιμο διάλυμα	SE/H/1562/001	022730	GE HEALTHCARE AS	CY
Dotagraf 0,5 mmol/ml ενέσιμο διάλυμα (μιας χρήσης)	DE/H/3944/001	022887	BAYER HELLAS SA	CY
Dotagraf 0,5 mmol/ml ενέσιμο διάλυμα (μιας χρήσης)	DE/H/3944/001	022887	BAYER HELLAS SA	CY
Dotagraf 0,5 mmol/ml ενέσιμο διάλυμα (πολλαπλών χρήσεων)	DE/H/3944/002	022888	BAYER HELLAS SA	CY
DOTAREM 0,5 mmol/ml ενέσιμο διάλυμα σε προγεμισμένες σύριγγες	NL/H/0381/003	022075	GUERBET	CY
DOTAREM 0,5 mmol/ml ενέσιμο διάλυμα σε φιαλίδια	NL/H/0381/001	022073	GUERBET	CY
DOTAREM 0,5 mmol/ml ενέσιμο διάλυμα σε φιαλίδια (για πολλαπλή χρήση)	NL/H/0381/002	022074	GUERBET	CY
Clariscan 0,5 mmol/ml injekční roztok	SE/H/1562/001	48/304/17-C	GE HEALTHCARE AS	CZ
Clariscan 0,5 mmol/ml injekční roztok v předplněné injekční stříkačce	SE/H/1562/002	48/305/17-C	GE HEALTHCARE AS	CZ
Cyclolux 279 mg/ml injekční roztok	DE/H/4015/001	48/493/15-C	SANOHEMIA PHARMAZEUTIKA GMBH	CZ
DOTAREM Injekční roztok	not available	48/1328/97-A/C	GUERBET	CZ
DOTAREM Injekční roztok v předplněné injekční stříkačce	not available	48/1328/97-B/C	GUERBET	CZ
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	97324.00.00	GE HEALTHCARE BUCHLER GMBH & CO. KG	DE
Clariscan 0,5 mmol/ml	SE/H/1562/002	97322.00.00	GE HEALTHCARE BUCHLER	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
Injektionslösung in einer Fertigspritze			GMBH & CO. KG	
Cyclolux 0,5 mmol/ml Injektionslösung	DE/H/4015/002	90905.00.00	SANOCHEMIA PHARMAZEUTIKA GMBH	DE
Cyclolux 0,5 mmol/ml Injektionslösung	DE/H/4015/001	90906.00.00	SANOCHEMIA PHARMAZEUTIKA GMBH	DE
Dotagita 0,5 mmol/ml Injektionslösung	not available	7000378.00.00	T2PHARMA GMBH	DE
Dotagraf 0,5 mmol/ml Injektionslösung	DE/H/3944/001	91052.00.00	JENAPHARM GMBH & CO KG	DE
Dotagraf 0,5 mmol/ml Injektionslösung	DE/H/3944/002	91053.00.00	JENAPHARM GMBH & CO KG	DE
Dotagraf 0,5 mmol/ml Injektionslösung	DE/H/3944/001	91052.00.00	JENAPHARM GMBH & CO KG	DE
Dota-MR 0,5 mmol/ml Injektionslösung	not available	96248.00.00	CONSENTIS DIAGNOSTICS GMBH	DE
Dota-MR 0,5 mmol/ml Injektionslösung	not available	96247.00.00	CONSENTIS DIAGNOSTICS GMBH	DE
Dota-MR 0,5 mmol/ml Injektionslösung	not available	96247.00.00	CONSENTIS DIAGNOSTICS GMBH	DE
DOTAREM 0,5 mmol/ml Injektionslösung in Durchstechflaschen (für Mehrfachentnahme) Wirkstoff: Gadotersäure	NL/H/0381/002	56813.00.00	GUERBET	DE
DOTAREM 0,5 mmol/ml Injektionslösung in Durchstechflaschen Wirkstoff: Gadotersäure	NL/H/0381/001	56812.00.00	GUERBET	DE
DOTAREM 0,5 mmol/ml Injektionslösung in Fertigspritzen Wirkstoff: Gadotersäure	NL/H/0381/003	56812.00.01	GUERBET	DE
DotaVision® 0,5 mmol/ml Injektionslösung	not available	96245.00.00	B.E.IMAGING.GMBH	DE
DotaVision® 0,5 mmol/ml	not available	96246.00.00	B.E.IMAGING.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
Injektionslösung				
Clariscan, injektionsvæske, opløsning	SE/H/1562/001	57390	GE HEALTHCARE AS	DK
Clariscan, injektionsvæske, opløsning i fyldt injektionssprøjte	SE/H/1562/002	57391	GE HEALTHCARE AS	DK
Dotagraf, injektionsvæske, opløsning (10 ml, 15 ml og 20 ml hætteglas)	DE/H/3944/001	57512	BAYER AB	DK
Dotagraf, injektionsvæske, opløsning (10 ml, 15 ml og 20 ml hætteglas)	DE/H/3944/001	57512	BAYER AB	DK
Dotagraf, injektionsvæske, opløsning (60 ml og 100 ml hætteglas)	DE/H/3944/002	57567	BAYER AB	DK
Dotarem, injektionsvæske, opløsning i enkelt dosisbeholder, i.v.	not available	17091	GUERBET	DK
Dotarem, injektionsvæske, opløsning i fyldt injektionssprøjte, enkelt dosisbeholder, i.v.	not available	34057	GUERBET	DK
Clariscan, 0,5 mmol/ml süstelähus	SE/H/1562/001	953117	GE HEALTHCARE AS	EE
Clariscan, 0,5 mmol/ml süstelähus süstlis	SE/H/1562/002	953217	GE HEALTHCARE AS	EE
Cyclolux 0,5 mmol/ml süstelähus	DE/H/4015/001	1074422	SANOCHEMIA PHARMAZEUTIKA GMBH	EE
Dotagraf 0,5 mmol/ml süstelähus	DE/H/3944/001	920016	BAYER AG	EE
Dotagraf 0,5 mmol/ml	DE/H/3944/002	919916	BAYER AG	EE



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
süstelahus				
Dotagraf 0,5 mmol/ml süstelahun	DE/H/3944/001	920016	BAYER AG	EE
Dotarem 0,5 mmol/ml, süstelahun	NL/H/0381/001	832113	GUERBET	EE
Dotarem 0,5 mmol/ml, süstelahun (mitmeannuseline)	NL/H/0381/002	832213	GUERBET	EE
Dotarem 0,5 mmol/ml, süstelahun süstlis	NL/H/0381/003	832313	GUERBET	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Dotascan 0,5 mmol/ml süstelahun	EE/H/0326/001	1045221	FARMAK INTERNATIONAL SP. Z O.O.	EE
Clariscan 0,5 mmol/mL solución inyectable EFG	SE/H/1562/001	81884	GE HEALTHCARE BIO-SCIENCES, S.A.U.	ES
Clariscan 0,5 mmol/mL solución inyectable en	SE/H/1562/002	81885	GE HEALTHCARE BIO-SCIENCES, S.A.U.	ES

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
jeringa precargada EFG				
Cyclolux 0,5 mmol/ml solución inyectable EFG	DE/H/4015/001	80133	SANOCHEMIA PHARMAZEUTIKA GMBH	ES
Cyclolux Rep 0,5 mmol/ml solución inyectable EFG	DE/H/4015/002	80134	SANOCHEMIA PHARMAZEUTIKA GMBH	ES
Dotagraf 0,5 mmol/ml solución inyectable EFG	DE/H/3944/002	80.561	BAYER HISPANIA SL	ES
Dotagraf 0,5 mmol/ml solución inyectable unidosis EFG	DE/H/3944/001	80.562	BAYER HISPANIA SL	ES
Dotagraf 0,5 mmol/ml solución inyectable unidosis EFG	DE/H/3944/001	80.562	BAYER HISPANIA SL	ES
Dotarem 0,5 mmol /ml solución inyectable en jeringa precargada	not available	67489	GUERBET	ES
Dotarem 0,5 mmol/ml solución inyectable en vial	not available	62.165	GUERBET	ES
Clariscan 0,5 mmol/ ml injektionsvätska, lösning	SE/H/1562/001	34027	GE HEALTHCARE AS	FI
Clariscan 0,5 mmol/ ml injektionsvätska, lösning, förfylld spruta	SE/H/1562/002	34028	GE HEALTHCARE AS	FI
Clariscan 0,5 mmol/ml injektioneste, liuos	SE/H/1562/001	34027	GE HEALTHCARE AS	FI
Clariscan 0,5 mmol/ml injektioneste, liuos, esitäytetty ruisku	SE/H/1562/002	34028	GE HEALTHCARE AS	FI
Dotarem 279,3 mg/ml injektioneste, liuos	not available	12086	GUERBET	FI
Dotarem 279,3 mg/ml injektioneste, liuos	not available	12086	GUERBET	FI
Dotarem 279,3 mg/ml injektioneste, liuos esitäytetty ruisku	not available	38455	GUERBET	FI
Dotarem 279,3 mg/ml	not available	38455	GUERBET	FI

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
injectioneste, liuos esitäytetty ruisku				
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable	NL/H/2028/001	34009 301 234 2 3	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable	NL/H/2028/001	34009 550 453 5 9	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable	NL/H/2028/001	34009 301 234 3 0	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable	NL/H/2028/001	34009 550 453 6 6	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable	NL/H/2028/001	34009 301 234 4 7	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable	NL/H/2028/001	34009 550 453 7 3	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable	NL/H/2028/001	34009 301 234 5 4	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable	NL/H/2028/001	34009 550 453 9 7	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable	NL/H/2028/001	34009 301 234 6 1	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable	NL/H/2028/001	34009 550 454 0 3	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 301 234 7 8	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL,	NL/H/2028/003	34009 301 234 8 5	GUERBET	FR

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
solution injectable en seringue pré-remplie				
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 301 234 9 2	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 088 1 6	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 088 2 3	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 088 3 0	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 088 4 7	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 224 4 7	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 224 5 4	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 224 6 1	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 224 7 8	GUERBET	FR

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
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 224 8 5	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 225 0 8	GUERBET	FR
ACIDE GADOTERIQUE GUERBET 0,5 mmol/mL, solution injectable en seringue pré-remplie	NL/H/2028/003	34009 302 225 1 5	GUERBET	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 918 8 3	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 918 9 0	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 919 0 6	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 919 2 0	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 919 1 3	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 919 5 1	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 919 3 7	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 919 4 4	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution	SE/H/1562/001	34009 300 920 0 2	GE HEALTHCARE SAS	FR

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
injectable				
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 919 6 8	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 919 7 5	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 919 8 2	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 920 1 9	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 919 9 9	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 920 2 6	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable	SE/H/1562/001	34009 300 920 3 3	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable en seringue pré-remplie	SE/H/1562/002	34009 300 918 1 4	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable en seringue pré-remplie	SE/H/1562/002	34009 300 918 2 1	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable en seringue pré-remplie	SE/H/1562/002	34009 300 918 5 2	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable en seringue pré-remplie	SE/H/1562/002	34009 300 918 4 5	GE HEALTHCARE SAS	FR

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
CLARISCAN 0,5 mmol/mL, solution injectable en seringue pré-remplie	SE/H/1562/002	34009 300 918 6 9	GE HEALTHCARE SAS	FR
CLARISCAN 0,5 mmol/mL, solution injectable en seringue pré-remplie	SE/H/1562/002	34009 300 918 7 6	GE HEALTHCARE SAS	FR
DOTAREM 0,5 mmol/mL, solution injectable	not available	34009 358 954 2 4	GUERBET	FR
DOTAREM 0,5 mmol/mL, solution injectable	not available	34009 331 713 4 6	GUERBET	FR
DOTAREM 0,5 mmol/mL, solution injectable	not available	34009 331 714 0 7	GUERBET	FR
DOTAREM 0,5 mmol/mL, solution injectable	not available	34009 331 715 7 5	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 279 470 2 5	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 279 469 4 3	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 300 045 0 0	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 300 045 1 7	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 358 953 6 3	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 338 403 0 3	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 338 404 7 1	GUERBET	FR
Dotarem 0,5 mmol/mL,	not available	34009 300 751 0 4	GUERBET	FR

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
solution injectable en seringue pré-remplie				
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 300 751 2 8	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 301 991 5 2	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 301 991 7 6	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 301 991 4 5	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 061 6 4	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 061 7 1	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 061 8 8	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 061 9 5	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 199 8 0	GUERBET	FR
Dotarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 199 7 3	GUERBET	FR
Pulsarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 365 7 4	GUERBET	FR
Pulsarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 365 8 1	GUERBET	FR



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
Pulsarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 365 9 8	GUERBET	FR
Pulsarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 366 0 4	GUERBET	FR
Pulsarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 366 1 1	GUERBET	FR
Pulsarem 0,5 mmol/mL, solution injectable en seringue pré-remplie	not available	34009 302 366 2 8	GUERBET	FR
Clariscan 0,5 mmol/ mL ενέσιμο διάλυμα	SE/H/1562/001	24622/13-11-2018	GE HEALTHCARE AS	GR
Clariscan 0,5 mmol/ mL ενέσιμο διάλυμα σε προγεμισμένη σύριγγα	SE/H/1562/002	64356/17/13-11-2018	GE HEALTHCARE AS	GR
Cyclolux 0,5 mmol ενέσιμο διάλυμα	DE/H/4015/001	938454/04-02-2021	SANOCHEMIA PHARMAZEUTIKA GMBH	GR
Dotagraf 0,5 mmol/ml ενέσιμο διάλυμα (μιας χρήσης)	DE/H/3944/001	112695/11-11-2020	BAYER HELLAS SA	GR
Dotagraf 0,5 mmol/ml ενέσιμο διάλυμα (μιας χρήσης)	DE/H/3944/001	112695/11-11-2020	BAYER HELLAS SA	GR
Dotagraf 0,5 mmol/ml ενέσιμο διάλυμα (πολλαπλών χρήσεων)	DE/H/3944/002	112696/11-11-2020	BAYER HELLAS SA	GR
DOTAREM 0,5 mmol/ml ενέσιμο διάλυμα σε προγεμισμένες σύριγγες	not available	1716/95/9-1-96	GUERBET	GR
DOTAREM 0,5 mmol/ml ενέσιμο διάλυμα σε φιαλίδια	not available	1716/95/9-1-96	GUERBET	GR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-01	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-02	GE HEALTHCARE AS	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
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-03	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-04	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-05	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-06	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-07	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-08	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-09	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-10	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-11	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju	SE/H/1562/001	HR-H-110014768-12	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju u napunjenoj štrcaljki	SE/H/1562/002	HR-H-420418028-01	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju u napunjenoj štrcaljki	SE/H/1562/002	HR-H-420418028-02	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju u napunjenoj štrcaljki	SE/H/1562/002	HR-H-420418028-03	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju u napunjenoj štrcaljki	SE/H/1562/002	HR-H-420418028-04	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju u napunjenoj štrcaljki	SE/H/1562/002	HR-H-420418028-05	GE HEALTHCARE AS	HR
Clariscan 0,5 mmol/ml otopina za injekciju u napunjenoj štrcaljki	SE/H/1562/002	HR-H-420418028-06	GE HEALTHCARE AS	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
Cyclolux 0,5 mmol/ml otopina za injekciju	DE/H/4015/001	HR-H-06283231	SANOCHEMIA PHARMAZEUTIKA GMBH	HR
Dotagraf 0,5 mmol/ml otopina za injekciju	DE/H/3944/001	HR-H-834184821	BAYER DOO	HR
Dotagraf 0,5 mmol/ml otopina za injekciju	DE/H/3944/001	HR-H-834184821	BAYER DOO	HR
DOTAGRAF LV 0,5 mmol/ml otopina za injekciju	DE/H/3944/002	HR-H-254395217	BAYER DOO	HR
Dotarem 0,5 mmol/ml otopina za injekciju.	not available	HR-H-730140520	PHARMACOL D.O.O.	HR
Dotarem 0,5 mmol/ml, otopina za injekciju u napunjenoj štrcaljki.	not available	HR-H-369514985	PHARMACOL D.O.O.	HR
Dotarem 0,5 mmol/ml, otopina za injekciju u napunjenoj štrcaljki.	not available	HR-H-369514985-02	PHARMACOL D.O.O.	HR
Dotarem 0,5 mmol/ml, otopina za injekciju u napunjenoj štrcaljki.	not available	HR-H-369514985-03	PHARMACOL D.O.O.	HR
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/01	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/08	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/04	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/07	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/05	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/03	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/06	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/02	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/09	GE HEALTHCARE AS	HU

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
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/10	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/11	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/12	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/13	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/14	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/15	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció	SE/H/1562/001	OGYI-T-23291/16	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció előretöltött fecskendőben	SE/H/1562/002	OGYI-T-23291/17	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció előretöltött fecskendőben	SE/H/1562/002	OGYI-T-23291/18	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció előretöltött fecskendőben	SE/H/1562/002	OGYI-T-23291/19	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció előretöltött fecskendőben	SE/H/1562/002	OGYI-T-23291/20	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció előretöltött fecskendőben	SE/H/1562/002	OGYI-T-23291/21	GE HEALTHCARE AS	HU
Clariscan 0,5 mmol/ml oldatos injekció előretöltött fecskendőben	SE/H/1562/002	OGYI-T-23291/22	GE HEALTHCARE AS	HU

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
CYCLOLUX 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/4015/001	OGYI-T-22877/06	SANOCHEMIA PHARMAZEUTIKA GMBH	HU
CYCLOLUX 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/4015/001	OGYI-T-22877/05	SANOCHEMIA PHARMAZEUTIKA GMBH	HU
CYCLOLUX 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/4015/001	OGYI-T-22877/04	SANOCHEMIA PHARMAZEUTIKA GMBH	HU
CYCLOLUX 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/4015/001	OGYI-T-22877/03	SANOCHEMIA PHARMAZEUTIKA GMBH	HU
CYCLOLUX 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/4015/001	OGYI-T-22877/02	SANOCHEMIA PHARMAZEUTIKA GMBH	HU
CYCLOLUX 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/4015/001	OGYI-T-22877/01	SANOCHEMIA PHARMAZEUTIKA GMBH	HU
CYCLOLUX 0,5 mmol/ml oldatos injekció, többadagos	DE/H/4015/002	OGYI-T-22877/09	SANOCHEMIA PHARMAZEUTIKA GMBH	HU
CYCLOLUX 0,5 mmol/ml oldatos injekció, többadagos	DE/H/4015/002	OGYI-T-22877/08	SANOCHEMIA PHARMAZEUTIKA GMBH	HU
CYCLOLUX 0,5 mmol/ml oldatos injekció, többadagos	DE/H/4015/002	OGYI-T-22877/07	SANOCHEMIA PHARMAZEUTIKA GMBH	HU
CYCLOLUX 0,5 mmol/ml oldatos injekció, többadagos	DE/H/4015/002	OGYI-T-22877/10	SANOCHEMIA PHARMAZEUTIKA GMBH	HU
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/01	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/02	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció,	DE/H/3944/001	OGYI-T-23115/05	BAYER AG	HU

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
egyadagos				
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/06	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/04	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/03	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/01	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/02	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/05	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/06	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/04	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, egyadagos	DE/H/3944/001	OGYI-T-23115/03	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, többadagos	DE/H/3944/002	OGYI-T-23115/07	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, többadagos	DE/H/3944/002	OGYI-T-23115/09	BAYER AG	HU
Dotagraf 0,5 mmol/ml oldatos injekció, többadagos	DE/H/3944/002	OGYI-T-23115/08	BAYER AG	HU
Dotagraf 0,5 mmol/ml	DE/H/3944/002	OGYI-T-23115/10	BAYER AG	HU

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
oldatos injekció, többadagos				
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/01	GUERBET	HU
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/02	GUERBET	HU
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/03	GUERBET	HU
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/04	GUERBET	HU
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/05	GUERBET	HU
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/06	GUERBET	HU
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/07	GUERBET	HU
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/08	GUERBET	HU
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/09	GUERBET	HU
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/10	GUERBET	HU
Dotarem 0,5 mmol/ml oldatos injekció	not available	OGYI-T-9156/11	GUERBET	HU
Clariscan 0.5 mmol/ mL solution for injection in pre-filled syringe	SE/H/1562/002	PA 0735/011/002	GE HEALTHCARE AS	IE
Clariscan 279.3 mg/ml solution for injection	SE/H/1562/001	PA0735/011/001	GE HEALTHCARE AS	IE
Cyclolux 279.32 mg/ml solution for injection	DE/H/4015/001	PA23317/001/001	SANOCHEMIA PHARMAZEUTIKA GMBH	IE
Dotagraf 279.32 mg/ml solution for injection	DE/H/3944/001	PA1410/082/001	BAYER LTD	IE
Dotagraf 279.32 mg/ml solution for injection	DE/H/3944/002	PA1410/082/002	BAYER LTD	IE
Dotagraf 279.32 mg/ml solution for injection	DE/H/3944/001	PA1410/082/001	BAYER LTD	IE
Dotarem 279.32 mg/ml	not available	PA0686/003/005	GUERBET	IE

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
solution for injection in pre-filled syringe				
Dotarem 279.32mg/ml solution for injection	not available	PA0686/003/002	GUERBET	IE
Clariscan 0,5 mmól/ml stungulyf, lausn í áfylltri sprautu.	SE/H/1562/002	IS/1/16/110/02	GE HEALTHCARE AS	IS
Clariscan 0,5 mmól/ml stungulyf, lausn.	SE/H/1562/001	IS/1/16/110/01	GE HEALTHCARE AS	IS
Dotagraf 0,5 mmól/ml stungulyf, lausn	DE/H/3944/002	IS/1/16/087/02	BAYER AB	IS
Dotagraf 0,5 mmól/ml, stungulyf, lausn	DE/H/3944/001	IS/1/16/087/01	BAYER AB	IS
Dotagraf 0,5 mmól/ml, stungulyf, lausn	DE/H/3944/001	IS/1/16/087/01	BAYER AB	IS
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977015	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977039	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977027	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977041	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977054	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977066	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977078	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977080	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977092	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977116	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977104	GE HEALTHCARE AS	IT
Claricyclíc 0,5 mmol/mL	SE/H/1562/001	044977128	GE HEALTHCARE AS	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
soluzione iniettabile				
Claricycllic 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977130	GE HEALTHCARE AS	IT
Claricycllic 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977142	GE HEALTHCARE AS	IT
Claricycllic 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977155	GE HEALTHCARE AS	IT
Claricycllic 0,5 mmol/mL soluzione iniettabile	SE/H/1562/001	044977167	GE HEALTHCARE AS	IT
Claricycllic 0,5 mmol/mL soluzione iniettabile in siringa preimpita	SE/H/1562/002	044977179	GE HEALTHCARE AS	IT
Claricycllic 0,5 mmol/mL soluzione iniettabile in siringa preimpita	SE/H/1562/002	044977181	GE HEALTHCARE AS	IT
Claricycllic 0,5 mmol/mL soluzione iniettabile in siringa preimpita	SE/H/1562/002	044977193	GE HEALTHCARE AS	IT
Claricycllic 0,5 mmol/mL soluzione iniettabile in siringa preimpita	SE/H/1562/002	044977205	GE HEALTHCARE AS	IT
Claricycllic 0,5 mmol/mL soluzione iniettabile in siringa preimpita	SE/H/1562/002	044977217	GE HEALTHCARE AS	IT
Claricycllic 0,5 mmol/mL soluzione iniettabile in siringa preimpita	SE/H/1562/002	044977229	GE HEALTHCARE AS	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849013	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849037	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849049	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849025	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849052	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di	DE/H/3944/001	043849064	BAYER SPA	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
soluzione iniettabile				
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/002	043849076	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/002	043849090	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/002	043849088	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/002	043849102	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849013	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849037	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849049	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849025	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849052	BAYER SPA	IT
Dotagraf 0,5 mmol/ml di soluzione iniettabile	DE/H/3944/001	043849064	BAYER SPA	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724109	GUERBET	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724022	GUERBET	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724034	GUERBET	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724046	GUERBET	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724073	GUERBET	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per	not available	029724085	GUERBET	IT

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uso endovenoso				
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724123	GUERBET	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724059	GUERBET	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724061	GUERBET	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724135	GUERBET	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724147	GUERBET	IT
DOTAREM 0,5 mmol/ml soluzione iniettabile per uso endovenoso	not available	029724150	GUERBET	IT
Clariscan 0,5 mmol/ml iniekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/001	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml iniekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/002	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml iniekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/003	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml iniekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/004	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml iniekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/005	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml iniekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/006	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml iniekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/007	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml iniekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/008	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml iniekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/009	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml	SE/H/1562/001	LT/1/17/4158/010	GE HEALTHCARE AS	LT

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
injekcinis tirpalas				
Clariscan 0,5 mmol/ml injekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/011	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml injekcinis tirpalas	SE/H/1562/001	LT/1/17/4158/012	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	SE/H/1562/002	LT/1/17/4158/013	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	SE/H/1562/002	LT/1/17/4158/014	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	SE/H/1562/002	LT/1/17/4158/015	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	SE/H/1562/002	LT/1/17/4158/016	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	SE/H/1562/002	LT/1/17/4158/017	GE HEALTHCARE AS	LT
Clariscan 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	SE/H/1562/002	LT/1/17/4158/018	GE HEALTHCARE AS	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/001	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/002	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/004	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/006	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/005	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/003	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/002	LT/1/16/3990/008	BAYER AG	LT
Dotagraf 0,5 mmol/ml	DE/H/3944/002	LT/1/16/3990/007	BAYER AG	LT

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
injekcinis tirpalas				
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/002	LT/1/16/3990/009	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/002	LT/1/16/3990/010	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/001	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/002	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/004	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/006	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/005	BAYER AG	LT
Dotagraf 0,5 mmol/ml injekcinis tirpalas	DE/H/3944/001	LT/1/16/3990/003	BAYER AG	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas	NL/H/0381/001	LT/1/14/3509/001	GUERBET	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas	NL/H/0381/001	LT/1/14/3509/002	GUERBET	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas	NL/H/0381/001	LT/1/14/3509/003	GUERBET	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas	NL/H/0381/001	LT/1/14/3509/004	GUERBET	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas	NL/H/0381/001	LT/1/14/3509/005	GUERBET	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas	NL/H/0381/002	LT/1/14/3509/006	GUERBET	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas	NL/H/0381/002	LT/1/14/3509/007	GUERBET	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	NL/H/0381/003	LT/1/14/3509/008	GUERBET	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	NL/H/0381/003	LT/1/14/3509/009	GUERBET	LT
DOTAREM 0,5 mmol/ml	NL/H/0381/003	LT/1/14/3509/010	GUERBET	LT

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
injekcinis tirpalas užpildytame švirkšte				
DOTAREM 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	NL/H/0381/003	LT/1/14/3509/013	GUERBET	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	NL/H/0381/003	LT/1/14/3509/012	GUERBET	LT
DOTAREM 0,5 mmol/ml injekcinis tirpalas užpildytame švirkšte	NL/H/0381/003	LT/1/14/3509/011	GUERBET	LT
Clariscan 0,5 mmol/ml Injektionslösung	SE/H/1562/001	2018020108	GE HEALTHCARE AS	LU
Clariscan 0,5 mmol/ml Injektionslösung in einer Fertigspritze	SE/H/1562/002	2018020109	GE HEALTHCARE AS	LU
Clariscan 0,5 mmol/ml, solution injectable	SE/H/1562/001	2018020108	GE HEALTHCARE AS	LU
Clariscan 0,5 mmol/ml, solution injectable en seringue préremplie	SE/H/1562/002	2018020109	GE HEALTHCARE AS	LU
Dotagraph 0,5 mmol/ml Injektionslösung (10 ml/15 ml/20 ml)	DE/H/3944/001	2017040083	BAYER SA NV	LU
Dotagraph 0,5 mmol/ml Injektionslösung (10 ml/15 ml/20 ml)	DE/H/3944/001	2017040083	BAYER SA NV	LU
Dotagraph 0,5 mmol/ml Injektionslösung (60 ml/100 ml)	DE/H/3944/002	2017040084	BAYER SA NV	LU
Dotagraph 0,5 mmol/ml solution injectable (10 ml/15 ml/20 ml)	DE/H/3944/001	2017040083	BAYER SA NV	LU
Dotagraph 0,5 mmol/ml solution injectable (10 ml/15 ml/20 ml)	DE/H/3944/001	2017040083	BAYER SA NV	LU
Dotagraph 0,5 mmol/ml solution injectable (60 ml/100 ml)	DE/H/3944/002	2017040084	BAYER SA NV	LU

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
ml/100 ml)				
Dotarem 0,5 mmol/ml, Injektionslösung	not available	2001086537	GUERBET	LU
Dotarem 0,5 mmol/ml, Injektionslösung	not available	2001086537	GUERBET	LU
Dotarem 0,5 mmol/mL, solution injectable	not available	2001086537	GUERBET	LU
Dotarem 0,5 mmol/mL, solution injectable	not available	2001086537	GUERBET	LU
Clariscan 0,5 mmol/ml šķīdums injekcijām	SE/H/1562/001	17-0238	GE HEALTHCARE AS	LV
Clariscan 0,5 mmol/ml šķīdums injekcijām pilnšļircē	SE/H/1562/002	17-0239	GE HEALTHCARE AS	LV
CYCLOLUX 0,5 mmol/ml šķīdums injekcijām	DE/H/4015/001	22-0162	SANOCHEMIA PHARMAZEUTIKA GMBH	LV
Dotagraf 0,5 mmol/ml šķīdums injekcijām	DE/H/3944/001	16-0205	BAYER AG	LV
Dotagraf 0,5 mmol/ml šķīdums injekcijām	DE/H/3944/001	16-0205	BAYER AG	LV
Dotagraf 0,5 mmol/ml šķīdums injekcijām (vairakkartejai lietošanai)	DE/H/3944/002	16-0206	BAYER AG	LV
DOTAREM 0,5 mmol/ml šķīdums injekcijām flakonos	NL/H/0381/001	14-0082	GUERBET	LV
DOTAREM 0,5 mmol/ml šķīdums injekcijām flakonos (vairākkārtējai lietošanai)	NL/H/0381/002	14-0083	GUERBET	LV
DOTAREM 0,5 mmol/ml šķīdums injekcijām pilnšļircēs	NL/H/0381/003	14-0081	GUERBET	LV
Clariscan 0.5 mmol/ mL solution for injection	SE/H/1562/001	MA023/00401	GE HEALTHCARE AS	MT
Clariscan 0.5 mmol/ mL solution for injection in	SE/H/1562/002	MA023/00402	GE HEALTHCARE AS	MT

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
pre-filled syringe				
Dotagraf 0.5 mmol/ml solution for injection	DE/H/3944/001	MA1354/00501	BAYER HELLAS SA	MT
Dotagraf 0.5 mmol/ml solution for injection	DE/H/3944/001	MA1354/00501	BAYER HELLAS SA	MT
Clariscan 0,5 mmol/ml, oplossing voor injectie	SE/H/1562/001	RVG 121624	GE HEALTHCARE AS	NL
Clariscan 0,5 mmol/ml, oplossing voor injectie in voorgevulde spuit.	SE/H/1562/002	RVG 121625	GE HEALTHCARE AS	NL
Cyclolux 0,5 mmol/ml, oplossing voor injectie	DE/H/4015/001	RVG 129452	SANOCHEMIA PHARMAZEUTIKA GMBH	NL
Dotagraf 0,5 mmol/ml (voor meervoudig gebruik), oplossing voor injectie	DE/H/3944/002	RVG 119005	BAYER B.V.	NL
Dotagraf 0,5 mmol/ml, oplossing voor injectie	DE/H/3944/001	RVG 119004	BAYER B.V.	NL
Dotagraf 0,5 mmol/ml, oplossing voor injectie	DE/H/3944/001	RVG 119004	BAYER B.V.	NL
DOTAREM 0,5 mmol/ml (voor meervoudig gebruik) oplossing voor injectie in injectieflacons.	NL/H/0381/002	RVG 27039	GUERBET	NL
DOTAREM 0,5 mmol/ml oplossing voor injectie in injectieflacons.	NL/H/0381/001	RVG 14203	GUERBET	NL
DOTAREM 0,5 mmol/ml oplossing voor injectie in voorgevulde spuit.	NL/H/0381/003	RVG 28743	GUERBET	NL
DOTAREM 0,5 mmol/ml oplossing voor injectie in voorgevulde spuit.	NL/H/0381/003	RVG 27040	GUERBET	NL
DOTAREM 0,5 mmol/ml oplossing voor injectie in voorgevulde spuit.	NL/H/0381/003	RVG 28744	GUERBET	NL
Gadoteerzuur Guerbet	NL/H/2028/002	RVG 107973	GUERBET	NL



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
0,5 mmol/ml, oplossing voor injectie in injectieflacons (voor meervoudig gebruik).				
Gadoteerzuur Guerbet 0,5 mmol/ml, oplossing voor injectie in injectieflacons.	NL/H/2028/001	RVG 107972	GUERBET	NL
Gadoteerzuur Guerbet 0,5 mmol/ml, oplossing voor injectie in voorgevulde spuit.	NL/H/2028/003	RVG 107974	GUERBET	NL
Clariscan 0,5 mmol/ml injeektionsvæske, oppløsning	SE/H/1562/001	16-11096	GE HEALTHCARE AS	NO
Clariscan 0,5 mmol/ml injeektionsvæske, oppløsning i ferdigfylt sprøyte	SE/H/1562/002	16-11097	GE HEALTHCARE AS	NO
Dotarem 279,3 mg/ml injeektionsvæske, oppløsning	not available	95-2155	GUERBET	NO
Clariscan, 0,5 mmol/ml, roztwór do wstrzykiwań	SE/H/1562/001	24388	GE HEALTHCARE AS	PL
Clariscan, 0,5 mmol/ml, roztwór do wstrzykiwań w ampułko-strzykawce	SE/H/1562/002	24389	GE HEALTHCARE AS	PL
Cyclolux multidose, 0,5 mmol/ml, roztwór do wstrzykiwań	DE/H/4015/002	22820	SANOCHEMIA PHARMAZEUTIKA GMBH	PL
Cyclolux, 0,5 mmol/ml, roztwór do wstrzykiwań	DE/H/4015/001	22819	SANOCHEMIA PHARMAZEUTIKA GMBH	PL
Dotagraf multidose, 0,5 mmol/ml, roztwór do wstrzykiwań	DE/H/3944/002	23556	BAYER AG	PL
Dotagraf, 0,5 mmol/ml, roztwór do wstrzykiwań	DE/H/3944/001	23555	BAYER AG	PL
Dotagraf, 0,5 mmol/ml,	DE/H/3944/001	23555	BAYER AG	PL

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
roztwór do wstrzykiwań				
DOTAREM multidose, 0,5 mmol/ml, roztwór do wstrzykiwań w fiolce (do wielokrotnego użycia)	NL/H/0381/002	21854	GUERBET	PL
DOTAREM, 0,5 mmol/ml, roztwór do wstrzykiwań w ampułko-strzykawce	NL/H/0381/003	21859	GUERBET	PL
DOTAREM, 0,5 mmol/ml, roztwór do wstrzykiwań w fiolce	NL/H/0381/001	21853	GUERBET	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL

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
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Gadoteric Acid Farmak, 0,5 mmol/ml, roztwór do wstrzykiwań	EE/H/0326/001	26955	FARMAK INTERNATIONAL SP. Z O.O.	PL
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5733035	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5733043	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5732425	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5733050	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5732417	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5733068	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5732409	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5733076	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5732979	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5733001	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5733027	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5733019	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5732946	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5732953	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5732375	GE HEALTHCARE AS	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
solução injetável				
Clariscan 0,5 mmol/ml, solução injetável	SE/H/1562/001	5732961	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável em seringa pré-cheia	SE/H/1562/002	5732359	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável em seringa pré-cheia	SE/H/1562/002	5733100	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável em seringa pré-cheia	SE/H/1562/002	5732367	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável em seringa pré-cheia	SE/H/1562/002	5733118	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável em seringa pré-cheia	SE/H/1562/002	5733126	GE HEALTHCARE AS	PT
Clariscan 0,5 mmol/ml, solução injetável em seringa pré-cheia	SE/H/1562/002	5733134	GE HEALTHCARE AS	PT
Cyclolux, 279.32 mg/ml Solução injetável	DE/H/4015/001	5850318	SANOCHEMIA PHARMAZEUTIKA GMBH	PT
Cyclolux, 279.32 mg/ml Solução injetável	DE/H/4015/001	5850326	SANOCHEMIA PHARMAZEUTIKA GMBH	PT
Cyclolux, 279.32 mg/ml Solução injetável	DE/H/4015/001	5850334	SANOCHEMIA PHARMAZEUTIKA GMBH	PT
Cyclolux, 279.32 mg/ml Solução injetável	DE/H/4015/001	5850342	SANOCHEMIA PHARMAZEUTIKA GMBH	PT
Cyclolux, 279.32 mg/ml Solução injetável	DE/H/4015/001	5850359	SANOCHEMIA PHARMAZEUTIKA GMBH	PT
Cyclolux, 279.32 mg/ml Solução injetável	DE/H/4015/001	5850367	SANOCHEMIA PHARMAZEUTIKA GMBH	PT
Dotagraf 0,5 mmol/ml solução injetável	DE/H/3944/001	5699319	BAYER PORTUGAL LDA	PT
Dotagraf 0,5 mmol/ml solução injetável	DE/H/3944/001	5699301	BAYER PORTUGAL LDA	PT
Dotagraf 0,5 mmol/ml	DE/H/3944/001	5699277	BAYER PORTUGAL LDA	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
solução injetável				
Dotagraf 0,5 mmol/ml solução injetável	DE/H/3944/002	5699269	BAYER PORTUGAL LDA	PT
Dotagraf 0,5 mmol/ml solução injetável	DE/H/3944/001	5699319	BAYER PORTUGAL LDA	PT
Dotagraf 0,5 mmol/ml solução injetável	DE/H/3944/001	5699301	BAYER PORTUGAL LDA	PT
Dotagraf 0,5 mmol/ml solução injetável	DE/H/3944/001	5699277	BAYER PORTUGAL LDA	PT
DOTAREM, 279,32 mg/ml, solução injetável	not available	3974888	GUERBET	PT
DOTAREM, 279,32 mg/ml, solução injetável	not available	8787903	GUERBET	PT
DOTAREM, 279,32 mg/ml, solução injetável	not available	8787937	GUERBET	PT
DOTAREM, 279,32 mg/ml, solução injetável	not available	8787945	GUERBET	PT
DOTAREM, 279,32 mg/ml, solução injetável	not available	8787929	GUERBET	PT
DOTAREM, 279,32 mg/ml, solução injetável	not available	8787911	GUERBET	PT
DOTAREM, 279,32 mg/ml, solução injetável	not available	3974680	GUERBET	PT
DOTAREM, 279,32 mg/ml, solução injetável	not available	3974789	GUERBET	PT
DOTAREM, 279,32 mg/ml, solução injetável	not available	5476825	GUERBET	PT
Dotarem, 279,32 mg/ml, solução injetável	not available	5801402	GUERBET	PT
Dotarem, 279,32 mg/ml, solução injetável	not available	5801451	GUERBET	PT
Dotarem, 279,32 mg/ml, solução injetável	not available	5801410	GUERBET	PT
Dotarem, 279,32 mg/ml, solução injetável	not available	5801436	GUERBET	PT
Dotarem, 279,32 mg/ml, solução injetável	not available	5801428	GUERBET	PT
Dotarem, 279,32 mg/ml, solução injetável	not available	5801444	GUERBET	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
solução injetável				
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/01	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/02	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/03	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/04	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/05	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/06	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/07	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/08	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/09	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/13	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/10	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/14	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/11	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/15	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/12	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă	SE/H/1562/001	14388/2022/16	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă în seringă preumplută	SE/H/1562/002	14389/2022/01	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă în	SE/H/1562/002	14389/2022/02	GE HEALTHCARE AS	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
seringă preumplută				
Clariscan 0,5 mmoli/ml soluție injectabilă în seringă preumplută	SE/H/1562/002	14389/2022/03	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă în seringă preumplută	SE/H/1562/002	14389/2022/04	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă în seringă preumplută	SE/H/1562/002	14389/2022/05	GE HEALTHCARE AS	RO
Clariscan 0,5 mmoli/ml soluție injectabilă în seringă preumplută	SE/H/1562/002	14389/2022/06	GE HEALTHCARE AS	RO
CYCLOLUX 0,5 mmol/ml soluție injectabilă	DE/H/4015/001	14807/2022/01	SANOCHEMIA PHARMAZEUTIKA GMBH	RO
CYCLOLUX 0,5 mmol/ml soluție injectabilă	DE/H/4015/001	14807/2022/02	SANOCHEMIA PHARMAZEUTIKA GMBH	RO
CYCLOLUX 0,5 mmol/ml soluție injectabilă	DE/H/4015/001	14807/2022/03	SANOCHEMIA PHARMAZEUTIKA GMBH	RO
CYCLOLUX 0,5 mmol/ml soluție injectabilă	DE/H/4015/001	14807/2022/04	SANOCHEMIA PHARMAZEUTIKA GMBH	RO
CYCLOLUX 0,5 mmol/ml soluție injectabilă	DE/H/4015/001	14807/2022/05	SANOCHEMIA PHARMAZEUTIKA GMBH	RO
CYCLOLUX 0,5 mmol/ml soluție injectabilă	DE/H/4015/001	14807/2022/06	SANOCHEMIA PHARMAZEUTIKA GMBH	RO
Dotagraf 0,5 mmol/ ml soluție injectabilă în flacon multidoză	DE/H/3944/002	12899/2020/01	BAYER AG	RO
Dotagraf 0,5 mmol/ ml soluție injectabilă în flacon multidoză	DE/H/3944/002	12899/2020/04	BAYER AG	RO
Dotagraf 0,5 mmol/ ml soluție injectabilă în flacon multidoză	DE/H/3944/002	12899/2020/03	BAYER AG	RO
Dotagraf 0,5 mmol/ ml soluție injectabilă în flacon multidoză	DE/H/3944/002	12899/2020/02	BAYER AG	RO
Dotagraf 0,5 mmol/ml	DE/H/3944/001	12898/2020/01	BAYER AG	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
soluție injectabilă în flacon unidoză				
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/03	BAYER AG	RO
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/06	BAYER AG	RO
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/05	BAYER AG	RO
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/02	BAYER AG	RO
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/04	BAYER AG	RO
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/01	BAYER AG	RO
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/03	BAYER AG	RO
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/06	BAYER AG	RO
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/05	BAYER AG	RO
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/02	BAYER AG	RO
Dotagraf 0,5 mmol/ml soluție injectabilă în flacon unidoză	DE/H/3944/001	12898/2020/04	BAYER AG	RO
Dotarem 0,5 mmol/ml soluție injectabilă multidoză	not available	1990/2009/01	GUERBET	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
Dotarem 0,5 mmol/ml soluție injectabilă multidoză	not available	1990/2009/02	GUERBET	RO
Dotarem 0,5 mmol/ml soluție injectabilă unidoză	not available	1989/2009/01	GUERBET	RO
Dotarem 0,5 mmol/ml soluție injectabilă unidoză	not available	1989/2009/02	GUERBET	RO
Dotarem 0,5 mmol/ml soluție injectabilă unidoză	not available	1989/2009/03	GUERBET	RO
Dotarem 0,5 mmol/ml soluție injectabilă unidoză	not available	1989/2009/04	GUERBET	RO
Dotarem 0,5 mmol/ml soluție injectabilă unidoză	not available	1989/2009/05	GUERBET	RO
Dotarem 0,5 mmol/ml, soluție injectabilă în seringă preumplută	not available	1988/2009/01	GUERBET	RO
Dotarem 0,5 mmol/ml, soluție injectabilă în seringă preumplută	not available	1988/2009/02	GUERBET	RO
Dotarem 0,5 mmol/ml, soluție injectabilă în seringă preumplută	not available	1988/2009/03	GUERBET	RO
Clariscan 0,5 mmol/ ml injektionsvätska, lösning	SE/H/1562/001	54433	GE HEALTHCARE AS	SE
Clariscan 0,5 mmol/ ml injektionsvätska, lösning, förfylld spruta	SE/H/1562/002	54434	GE HEALTHCARE AS	SE
Dotagraf (stor injektionsflaska) 0,5 mmol/ml injektionsvätska, lösning	DE/H/3944/002	54615	BAYER AB	SE
Dotagraf 0,5 mmol/ml injektionsvätska, lösning	DE/H/3944/001	54559	BAYER AB	SE

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
Dotagraf 0,5 mmol/ml injektionsvätska, lösning	DE/H/3944/001	54559	BAYER AB	SE
Dotarem 279,3 mg/ml injektionsvätska, lösning	not available	12585	GUERBET	SE
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/003	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/001	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/002	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/006	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/005	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/007	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/004	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/015	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/008	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/017	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/016	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/018	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/019	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/022	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/021	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje	SE/H/1562/001	H/17/02409/020	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje v	SE/H/1562/002	H/17/02409/014	GE HEALTHCARE AS	SI

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napolnjeni injekcijski brizgi				
Clariscan 0,5 mmol/ml raztopina za injiciranje v napolnjeni injekcijski brizgi	SE/H/1562/002	H/17/02409/010	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje v napolnjeni injekcijski brizgi	SE/H/1562/002	H/17/02409/009	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje v napolnjeni injekcijski brizgi	SE/H/1562/002	H/17/02409/011	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje v napolnjeni injekcijski brizgi	SE/H/1562/002	H/17/02409/012	GE HEALTHCARE AS	SI
Clariscan 0,5 mmol/ml raztopina za injiciranje v napolnjeni injekcijski brizgi	SE/H/1562/002	H/17/02409/013	GE HEALTHCARE AS	SI
Cyclolux 0,5 mmol/ml raztopina za injiciranje	DE/H/4015/001	H/23/02965/001-006	SANOCHEMIA PHARMAZEUTIKA GMBH	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/001	BAYER D.O.O	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/003	BAYER D.O.O	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/005	BAYER D.O.O	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/002	BAYER D.O.O	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/004	BAYER D.O.O	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/006	BAYER D.O.O	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/001	BAYER D.O.O	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
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/003	BAYER D.O.O	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/005	BAYER D.O.O	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/002	BAYER D.O.O	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/004	BAYER D.O.O	SI
Dotagraf 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/001	H/17/02300/006	BAYER D.O.O	SI
Dotagraf LV 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/002	H/17/02300/009	BAYER D.O.O	SI
Dotagraf LV 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/002	H/17/02300/007	BAYER D.O.O	SI
Dotagraf LV 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/002	H/17/02300/010	BAYER D.O.O	SI
Dotagraf LV 0,5 mmol/ml raztopina za injiciranje	DE/H/3944/002	H/17/02300/008	BAYER D.O.O	SI
DOTAREM 0,5 mmol/ml raztopina za injiciranje	not available	H/00/00508/003	GUERBET	SI
DOTAREM 0,5 mmol/ml raztopina za injiciranje	not available	H/00/00508/001	GUERBET	SI
DOTAREM 0,5 mmol/ml raztopina za injiciranje	not available	H/00/00508/002	GUERBET	SI
Clariscan 0,5 mmol/ml injekčný roztok	SE/H/1562/001	48/0417/17-S	GE HEALTHCARE AS	SK
Clariscan 0,5 mmol/ml injekčný roztok naplnený v injekcnej striekacke	SE/H/1562/002	48/0418/17-S	GE HEALTHCARE AS	SK
Cyclolux 0,5 mmol/ml injekčný roztok	DE/H/4015/001	48/0436/15-S	SANOCHEMIA PHARMAZEUTIKA GMBH	SK
Cyclolux Multi 0,5 mmol/ml injekčný roztok	DE/H/4015/002	48/0437/15-S	SANOCHEMIA PHARMAZEUTIKA GMBH	SK
Dotagraf 0,5 mmol/ml	DE/H/3944/001	48/0453/16-S	BAYER AG	SK

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injekčný roztok				
Dotagraf 0,5 mmol/ml injekčný roztok	DE/H/3944/001	48/0453/16-S	BAYER AG	SK
Dotagraf viacdávkový 0,5 mmol/ml injekčný roztok	DE/H/3944/002	48/0454/16-S	BAYER AG	SK
DOTAREM 0,5 mmol/ml injekčný roztok naplnený v injekčnej striekačke	NL/H/0381/003	48/0503/13-S	GUERBET	SK
DOTAREM 0,5 mmol/ml injekčný roztok v injekčných liekovkách	NL/H/0381/001	48/0501/13-S	GUERBET	SK
DOTAREM 0,5 mmol/ml injekčný roztok v injekčných liekovkách (na viacnásobné použitie)	NL/H/0381/002	48/0502/13-S	GUERBET	SK
Cyclolux 0.5 mmol/ml solution for injection	DE/H/4015/001	PL 52910/0001	SANOCHEMIA PHARMAZEUTIKA GMBH	XI
Dotagraf 0.5 mmol/ml solution for injection	DE/H/3944/001	PL 00010/0590	BAYER PLC	XI
Dotagraf 0.5 mmol/ml solution for injection	DE/H/3944/001	PL 00010/0590	BAYER PLC	XI
Dotarem 279.32 mg/ml Solution for injection in glass vials	not available	PL 12308/0016	GUERBET	XI
Dotarem 279.32 mg/ml Solution for injection in pre-filled syringes	not available	PL 12308/0017	GUERBET	XI