



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2016
EMA/194278/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: Gadoteric acid (IV and intravascular formulations)

Procedure no.: PSUSA/00001506/201504



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
Dotagita	DE/H/3604/001/DC	04350106	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotagita	DE/H/3604/001/DC	3400930000625	Agfa Healthcare Imaging Agents Gmbh	France
Dotagita	DE/H/3604/001/DC	849414	Agfa Healthcare Imaging Agents Gmbh	Estonia
Dotagita	DE/H/3604/001/DC	BE461200	Agfa Healthcare Imaging Agents Gmbh	Belgium
Dotagita	DE/H/3604/001/DC	LT/1/14/3608/001-010	Agfa Healthcare Imaging Agents Gmbh	Lithuania
Dotagita	DE/H/3604/001/DC DE/H/3605/001/DC	7007/2014/01-02-03-04- 05-06-07-08-09-10 7008/2014/01-02-03-04	Agfa Healthcare Imaging Agents Gmbh	Romania
Dotagita	DE/H/3604/001/DC DE/H/3605/001/DC DE/H/3851/001/DC	87515.00.00 87516.00.00 89790.00.00	Agfa Healthcare Imaging Agents Gmbh	Germany
Dotagita	DE/H/3851/001/DC	79232	Agfa Healthcare Imaging Agents Gmbh	Spain
Dotagita	DE/H/3851/001/DC	PL 33127/0005	Agfa Healthcare Imaging Agents Gmbh	United Kingdom
Dotamulti	DE/H/3605/001/DC	043502020	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotarem		029724022 029724034 029724046 029724059 029724061 029724073 029724085 029724109 029724123	Guerbet	Italy
Dotarem		1-21996	Guerbet	Austria
Dotarem		12086	Guerbet	Finland
Dotarem		12585	Guerbet	Sweden
Dotarem		17091 34057	Guerbet	Denmark

Dotarem		1716/95/09-01-1996 50133/10/12-2011	Guerbet	Greece
Dotarem		1988/2009/01-02-03 1989/2009/01-02-03-04-05 1990/2009/01-02	Guerbet	Romania
Dotarem		2001086537 0252611 0152453 0152467 0305681 0355585 0210821 0210834	Guerbet	Luxembourg
Dotarem		34009 279 469 4 3 34009 279 470 2 5 34009 300 045 0 0 34009 300 045 1 7 34009 338 403 0 3 34009 338 404 7 1 34009 358 953 6 3	Guerbet	France
Dotarem		34009 331 713 4 6 34009 331 714 0 7 34009 331 715 7 5 34009 358 954 2 4	Guerbet	France
Dotarem		3974680 3974789 3974888 8787903 8787911 8787929 8787937 8787945	A. Martins & Fernandes, S.A.	Portugal
Dotarem		48/1328/97-A/C 48/1328/97-B/C	Guerbet	Czech Republic
Dotarem		5476825	A. Martins & Fernandes, S.A.	Portugal
Dotarem		62.165 67489	Guerbet	Spain

Dotarem		95-2155	Guerbet	Norway
Dotarem		BE149353 BE149362 BE149371 BE169531 BE169547 BE184615 BE226055 BE254992	Guerbet	Belgium
Dotarem		OGYI-T-9156/01 OGYI-T-9156/02 OGYI-T-9156/03 OGYI-T-9156/04 OGYI-T-9156/05	Guerbet	Hungary
Dotarem		PA 0686/003/002 PA 0686/003/005	Guerbet	Ireland
Dotarem		UP/I-530-09/09-01/166 UP/I-530-09/11-02/07	Pharmacol D.O.O.	Croatia
Dotarem	NL/H/0381/001 NL/H/0381/002	LT/1/14/3509/001 LT/1/14/3509/002 LT/1/14/3509/003 LT/1/14/3509/004 LT/1/14/3509/005 LT/1/14/3509/006 LT/1/14/3509/007	Guerbet	Lithuania
Dotarem	NL/H/0381/001 NL/H/0381/002 NL/H/0381/003	14-0081 14-0082 14-0083	Guerbet	Latvia
Dotarem	NL/H/0381/001 NL/H/0381/002 NL/H/0381/003	21853 21854 21859	Guerbet	Poland
Dotarem	NL/H/0381/001 NL/H/0381/002 NL/H/0381/003	22073 22074 22075	Guerbet	Cyprus
Dotarem	NL/H/0381/001 NL/H/0381/002 NL/H/0381/003	48/0501/13-S 48/0502/13-S 48/0503/13-S	Guerbet	Slovakia

Dotarem	NL/H/0381/001 NL/H/0381/002 NL/H/0381/003	56812.00.00 56812.00.01 56813.00.00	Guerbet	Germany
Dotarem	NL/H/0381/001 NL/H/0381/002 NL/H/0381/003	832113 832213 832313	Guerbet	Estonia
Dotarem	NL/H/0381/001 NL/H/0381/002 NL/H/0381/003	RVG 14203 RVG 27039 RVG 27040 RVG 28743 RVG 28744	Guerbet Nederland Bv	Netherlands
Dotarem	NL/H/0381/003	LT/1/14/3509/008 LT/1/14/3509/009 LT/1/14/3509/010	Guerbet	Lithuania
Dotaspin	NL/H/2028/001 NL/H/2028/002 NL/H/2028/003	82410.00.00 82411.00.00 82412.00.00	Guerbet	Germany
Gadoteerzuur Guerbet	NL/H/2028/001 NL/H/2028/002 NL/H/2028/003	RVG 107 974 RVG 107972 RVG 107973	Guerbet	Netherlands
Dotarem	NL/H/0381/001 NL/H/0381/002 NL/H/0381/003	20140129 20140141 20140142	Guerbet	Bulgaria
Dotarem		12308/0017 12308/0016	Guerbet	United Kingdom
Dotagita 0,5 mmol/ml oplossing voor injectie	DE/H/3604/01/DC	BE461217	Agfa Healthcare Imaging Agents Gmbh	Belgium
Dotagita 0,5 mmol/ml oplossing voor injectie	DE/H/3604/01/DC	BE461226	Agfa Healthcare Imaging Agents Gmbh	Belgium
Dotagita 0,5 mmol/ml oplossing voor injectie	DE/H/3604/01/DC	BE461235	Agfa Healthcare Imaging Agents Gmbh	Belgium
Dotagita 0,5 mmol/ml oplossing voor injectie	DE/H/3604/01/DC	BE461244	Agfa Healthcare Imaging Agents Gmbh	Belgium
Dotagita 0,5 mmol/ml solution injectable	DE/H/3604/01/DC	3400930000632	Agfa Healthcare Imaging Agents Gmbh	France
Dotagita 0,5 mmol/ml solution injectable	DE/H/3604/01/DC	3400930000656	Agfa Healthcare Imaging Agents Gmbh	France
Dotagita 0,5 mmol/ml solution injectable	DE/H/3604/01/DC	3400930000663	Agfa Healthcare Imaging Agents Gmbh	France

Dotagita 0,5 mmol/ml solution injectable	DE/H/3604/01/DC	3400930000629	Agfa Healthcare Imaging Agents Gmbh	France
Dotagita 0,5 mmol/ml solution injectable	DE/H/3604/01/DC	3400930000636	Agfa Healthcare Imaging Agents Gmbh	France
Dotagita 0,5 mmol/ml solution injectable	DE/H/3604/01/DC	3400930000643	Agfa Healthcare Imaging Agents Gmbh	France
Dotagita 0,5 mmol/ml solution injectable	DE/H/3604/01/DC	3400930000650	Agfa Healthcare Imaging Agents Gmbh	France
Dotagita 0,5 mmol/mL soluzione iniettabile	DE/H/3604/01/DC	043501028	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotagita 0,5 mmol/mL soluzione iniettabile	DE/H/3604/01/DC	043501030	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotagita 0,5 mmol/mL soluzione iniettabile	DE/H/3604/01/DC	043501042	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotagita 0,5 mmol/mL soluzione iniettabile	DE/H/3604/01/DC	043501055	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotagita 0,5 mmol/mL soluzione iniettabile	DE/H/3604/01/DC	043501067	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotagita 0,5 mmol/mL soluzione iniettabile	DE/H/3604/01/DC	043501079	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotagita 0,5 mmol/mL soluzione iniettabile	DE/H/3604/01/DC	043501081	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotagita 0,5 mmol/mL soluzione iniettabile	DE/H/3604/01/DC	043501093	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotagita 0,5 mmol/mL soluzione iniettabile	DE/H/3604/01/DC	043501105	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotamulti 0,5 mmol/mL	DE/H/3604/01/DC	043502018	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotamulti 0,5 mmol/mL	DE/H/3604/01/DC	043502032	Agfa Healthcare Imaging Agents Gmbh	Italy
Dotamulti 0,5 mmol/mL	DE/H/3604/01/DC	043502044	Agfa Healthcare Imaging Agents Gmbh	Italy