



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2021
EMA/702111/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: gadoteric acid (intra articular formulation)

Procedure no.: PSUSA/00001505/202004



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
Artirem 0,0025 mmol/ml Injektionslösung	not available	1-26350	GUERBET	Austria
Artirem 0,0025 mmol/ml Injektionslösung	not available	BE240502	GUERBET	Belgium
Artirem 0,0025 mmol/ml Injektionslösung	not available	2003040009 / 0345382	GUERBET	Luxemburg
ARTIREM 0,0025 mmol/ml Injektionslösung in Fertigspritzen	NL/H/0381/006	59439.00.00	GUERBET	Germany
Artirem 0,0025 mmol/ml, oplossing voor injectie	not available	BE240502	GUERBET	Belgium
Artirem 0,0025 mmol/ml, solution injectable	not available	BE240502	GUERBET	Belgium
ARTIREM 0,0025 mmol/mL, solution injectable	not available	34009 359 913 8 6	GUERBET	France
Artirem 0,0025 mmol/ml, solution injectable	not available	2003040009 / 0345382	GUERBET	Luxemburg
Artirem, 0,0025 mmol/ml oplossing voor injectie in voorgevulde spuit.	NL/H/0381/006	RVG 27348	GUERBET	The Netherlands

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 Arthro, injektionsvæske, opløsning i fyldt engangssprøjte, til intraartikulær anvendelse, enkeldosisbeholder	not available	32833	GUERBET	Denmark
DOTAREM® 0,0025 mmol/ml, soluzione iniettabile per uso intra- articolare	not available	029724097	GUERBET	Italy