



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2016
EMA/PRAC/4354/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: gadobutrol

Procedure No.: PSUSA/00001502/201504



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
Gadovist		02-0070	Bayer Pharma Ag	Latvia
Gadovist		3765/2003/01 & 3765/2003/02 & 3765/2003/03 & 3765/2003/04	Bayer Pharma Ag	Romania
Gadovist		3765/2003/05 & 3765/2003/06 & 3765/2003/07	Bayer Pharma Ag	Romania
Gadovist		441604	Bayer Pharma Ag	Estonia
Gadovist		48/0046/04-S	Bayer Pharma Ag	Slovakia
Gadovist		48/535/00-A/C & 48/535/00-B/C	Bayer Pharma Ag	Czech Republic
Gadovist		H/03/00664/004	Bayer Pharma Ag	Slovenia
Gadovist		H/03/00664/001 & H/03/00664/002 & H/03/00664/003 & H/03/00664/005	Bayer Pharma Ag	Slovenia
Gadovist		8991	Bayer Pharma Ag	Poland
Gadovist		LT/1/03/2358/001 & LT/1/03/2358/002 & LT/1/03/2358/003 & LT/1/03/2358/004 & LT/1/03/2358/005 & LT/1/03/2358/006 & LT/1/03/2358/007 & LT/1/03/2358/008 & LT/1/03/2358/009 & LT/1/03/2358/010 & LT/1/03/2358/011 & LT/1/03/2358/012 & LT/1/03/2358/013 & LT/1/03/2358/014 & LT/1/03/2358/015 & LT/1/03/2358/016 & LT/1/03/2358/017 & LT/1/03/2358/018 & LT/1/03/2358/019 & LT/1/03/2358/020 & LT/1/03/2358/021 & LT/1/03/2358/022 & LT/1/03/2358/023 & LT/1/03/2358/024 & LT/1/03/2358/025 & LT/1/03/2358/026	Bayer Pharma Ag	Lithuania
Gadovist		MTNR. 970380 (IS)	Bayer Pharma Ag	Iceland
Gadovist		OGYI-T-7793/01 & OGYI-T-7793/02 & OGYI-T-7793/04 & OGYI-T-7793/05	Bayer Pharma Ag	Hungary
Gadovist	DE/H/3372/001	034964104 & 034964116 & 034964128 & 034964130 & 034964229 & 034964231	Bayer Spa	Italy
Gadovist	DE/H/3372/001	034964142 & 034964155 & 034964167 & 034964179 & 034964181	Bayer Spa	Italy

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Gadovist	DE/H/3372/001	034964193 & 034964205 & 034964217	Bayer Spa	Italy
Gadovist	DE/H/3372/001	1-23810 & 1-24111	Bayer Austria Gmbh	Austria
Gadovist	DE/H/3372/001	15540 & 16261	Bayer Oy	Finland
Gadovist	DE/H/3372/001	279 081-6 & 355 583-3 & 355 585-6 & 355 586-2 & 355 587-9 & 562 945-8 & 562 946-4 & 562 947-0 & 562 948-7 & 586 860-2	Bayer Healthcare	France
Gadovist	DE/H/3372/001	3248283 & 3248382 & 3248481 & 3248580 & 3248689 & 3248788 & 3248887 & 3248986 & 3483682	Lusal Lda	Portugal
Gadovist	DE/H/3372/001	32842/24-5-2011	Bayer Hellas Sa	Greece
Gadovist	DE/H/3372/001	3482882 & 3482981 & 3483088 & 3483187 & 3483286 & 3483385 & 3483484 & 3483583 & 3483781	Lusal Lda	Portugal
Gadovist	DE/H/3372/001	360 802-1 & 360 803-8 & 360 804-4 & 370 141-8 & 370 142-4 & 393 130-2 & 393 131-9 & 393 132-5 & 564 570-1 & 564 571-8 & 564 572-4 & 567 175-6 & 567 176-2 & 574 796-2 & 574 797-9 & 574 798-5	Bayer Healthcare	France
Gadovist	DE/H/3372/001	5101027 & 5101035	Lusal Lda	Portugal
Gadovist	DE/H/3372/001	BE429161	Bayer Sa Nv	Belgium
Gadovist	DE/H/3372/001	BE429161 & BE429177 & BE429186 & BE456942	Bayer Sa Nv	Belgium
Gadovist	DE/H/3372/001	BE429186	Bayer Sa Nv	Belgium
Gadovist	DE/H/3372/001	PA1410/018/001 & PA1410/018/003	Bayer Ltd	Ireland
Gadovist	DE/H/3372/001	PA1410/018/002	Bayer Ltd	Ireland
Gadovist	DE/H/3372/001	PA1410/18/4	Bayer Ltd	Ireland
Gadovist	DE/H/3372/001	PL 00010/0535	Bayer Plc	United Kingdom

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Gadovist	DE/H/3372/001 & DE/H/3372/01-02	2001010005	Bayer Sa Nv	Luxembourg
Gadovist	DE/H/3372/01-02	00-1088 VIAL & 00-7978 PFS	Bayer Pharma Ag	Norway
Gadovist	DE/H/3372/01-02	0442/01010005 & 2001030022	Bayer Sa Nv	Luxembourg
Gadovist	DE/H/3372/01-02	16229 & 16790	Bayer Pharma Ag	Sweden
Gadovist	DE/H/3372/01-02	31449 & 31988	Bayer Pharma Ag	Denmark
Gadovist	DE/H/3372/01-02	40252.00.00 & 49627.01.00	Bayer Vital Gmbh	Germany
Gadovist	DE/H/3372/01-02	63.535 & 63.898	Bayer Hispania Sl	Spain
Gadovist	DE/H/3372/01-02	BE217077 & BE217086 & BE221094 & BE266323 & BE266332 & BE266341 & BE320686 & BE320695 & BE320704 & BE429186	Bayer Sa Nv	Belgium
Gadovist	DE/H/3372/01-02	HR-H-640080282-01 & HR-H-640080282-02 & HR-H-640080282-03 & HR-H-640080282-04 & HR-H-640080282-05 & HR-H-640080282-06 & HR-H-640080282-07 & HR-H-640080282-08 & HR-H-640080282-09 & HR-H-640080282-10 & HR-H-860656850-01 & HR-H-860656850-02 & HR-H-860656850-03 & HR-H-860656850-04 & HR-H-860656850-05 & HR-H-860656850-06 & HR-H-860656850-07 & HR-H-860656850-08 & HR-H-860656850-09 & HR-H-860656850-10 & HR-H-860656850-11 & HR-H-860656850-12 & HR-H-860656850-13 & HR-H-860656850-14 & HR-H-860656850-15 & HR-H-860656850-16	Bayer Doo	Croatia
Gadovist	DE/H/3372/01-02	PL 00010/0536	Bayer Plc	United Kingdom
Gadovist	DE/H/3372/01-02	RVG 25318 VIAL & RVG 26035 PFS	Bayer Bv	Netherlands
Gadovist Pfs	DE/H/3372/01-02	32843/24-5-2011 PFS	Bayer Hellas Sa	Greece

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гадовист		20021053 & 20090440	Bayer Pharma Ag	Bulgaria
Gadovist 1.0 mmol/ml solution for injection in prefilled syringe/cartridge		AA513/01201	Schering Health Care Ltd.	Malta
Gadovist 1.0 mmol/ml solution for injection		AA513/01202	Bayer PLC	Malta