



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management and Committees Support Division

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the Member States for gadolinium containing medicinal products

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1437

Optimark EMEA/H/A-31/1437/C/000745/0034



Nationally authorised medicinal products

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Austria	Bayer Austria Gmbh	Dotagraf	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Austria	Bayer Austria Gmbh	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Austria	Bayer Austria Gmbh	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	Solution for injection	Intraarticular use
Austria	Bayer Austria Gmbh	Magnevist	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Austria	Bayer Austria Gmbh	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Austria	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Austria	Bracco Imaging S.P.A.	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Austria	Ge Healthcare Handels Gmbh	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Austria	Guerbet	Artirem	Gadoteric Acid 1.397mg/MI	Solution for injection	Intraarticular use
Austria	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Austria	Sanochemia Pharmazeutika Ag	Cyclolux	Gadoteric Acid 0.5mmol/MI	Solution for injection	Intravenous use
Austria	Sanochemia Pharmazeutika Ag	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Belgium	Agfa Healthcare Imaging Agents Gmbh	Dotagita	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Belgium	Bayer Sa Nv	Dotagraph	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Belgium	Bayer Sa Nv	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Belgium	Bayer Sa Nv	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Belgium	Bayer Sa Nv	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Belgium	Bracco Imaging Deutschland Gmbh	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Belgium	Bracco Imaging Deutschland Gmbh	Multihance	Gadobenate Dimeglumine 10580mg/20 MI	Solution for injection in pre-filled syringe	Intravenous use
Belgium	Bracco Imaging Deutschland Gmbh	Multihance	Gadobenate Dimeglumine 5290mg/10 MI	Solution for injection in pre-filled syringe	Intravenous use
Belgium	Bracco Imaging Deutschland Gmbh	Multihance	Gadobenate Dimeglumine 7935mg/15 MI	Solution for injection in pre-filled syringe	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Belgium	Bracco Imaging Deutschland Gmbh	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Belgium	Ge Healthcare Bvba	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Belgium	Guerbet	Artirem	Gadoteric Acid 1.397mg/MI	Solution for injection	Intraarticular use
Belgium	Guerbet	Dotarem	Meglumine Gadoterate 0.5mmol/MI	Solution for injection	Intravenous use
Bulgaria	Bayer Pharma Ag	гадовист	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Bulgaria	Bayer Pharma Ag	магневист	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Bulgaria	Bayer Pharma Ag	примовист	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Bulgaria	Ge Healthcare As	омнискен	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Bulgaria	Guerbet	дотарем	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Bulgaria	Guerbet	дотарем	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Bulgaria	Sanochemia Pharmazeutika Ag	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Croatia	Agfa Healthcare Imaging Agents Gmbh	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Croatia	Bayer Doo	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Croatia	Bayer Doo	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Croatia	Bayer Doo	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Croatia	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Croatia	Ge Healthcare D.O.O.	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Croatia	Pharmacol D.O.O.	Dotarem	Gadoteric Acid 27.932g/100 MI	Solution for injection	Intravenous use
Croatia	Pharmacol D.O.O.	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Croatia	Pharmacol D.O.O.	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Cyprus	Bayer Hellas Sa	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Cyprus	Bayer Hellas Sa	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Cyprus	Bayer Hellas Sa	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Cyprus	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Cyprus	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Cyprus	Phadisco Ltd	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Czech Republic	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Czech Republic	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Czech Republic	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Czech Republic	Bracco Imaging Deutschland Gmbh	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Czech Republic	Bracco Imaging Deutschland Gmbh	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Czech Republic	Bracco Imaging Deutschland Gmbh	Prohance	Gadoteridol 279.3mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Czech Republic	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Czech Republic	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Czech Republic	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Czech Republic	Sanochemia Pharmazeutika Ag	Cyclolux	Gadoteric Acid 0.5 Milli Molar / MI	Solution for injection	Intravenous use
Denmark	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Denmark	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	Solution for injection	Intraarticular use
Denmark	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Denmark	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Denmark	Bracco International Bv	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Denmark	Ge Healthcare As	Omniscan	Gadodiamide 0.5mmol/MI	Solution for injection	Intravenous use
Denmark	Guerbet	Dotarem	Gadoteric Acid 279.3mg/MI	Solution for injection	Intravenous use
Denmark	Guerbet	Dotarem	Gadoteric Acid 279.3mg/MI	Solution for injection in pre-filled syringe	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Denmark	Guerbet	Dotarem Arthro	Gadoteric Acid 1.397mg/MI	Solution for injection in pre-filled syringe	Intraarticular use
Estonia	Agfa Healthcare Imaging Agents Gmbh	Dotagita	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Estonia	Agfa Healthcare Imaging Agents Gmbh	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Estonia	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Estonia	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Estonia	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Estonia	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Estonia	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Estonia	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Finland	Bayer Oy	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Finland	Bayer Oy	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Finland	Bayer Oy	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Finland	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Finland	Bracco International Bv	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Finland	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
France	Agfa Healthcare Imaging Agents GmbH	Dotagita	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
France	Bayer Healthcare	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
France	Bayer Healthcare	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	Solution for injection in pre-filled syringe	Intraarticular use
France	Bayer Healthcare	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
France	Bracco Imaging France	Multihance	Gadobenate Dimeglumine 10580mg/20 MI	Solution for injection	Intravenous use
France	Bracco Imaging France	Multihance	Gadobenate Dimeglumine 2645mg/5 MI	Solution for injection	Intravenous use
France	Bracco Imaging France	Multihance	Gadobenate Dimeglumine 5290mg/10 MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
France	Bracco Imaging France	Multihance	Gadobenate Dimeglumine 7935mg/15 MI	Solution for injection	Intravenous use
France	Bracco Imaging France	Multihance	Gadobenate Dimeglumine 10580mg/20 MI	Solution for injection in pre-filled syringe	Intravenous use
France	Bracco Imaging France	Prohance	Gadoteridol 1396.5mg/5 MI	Solution for injection	Intravenous use
France	Bracco Imaging France	Prohance	Gadoteridol 2793mg/10 MI	Solution for injection	Intravenous use
France	Bracco Imaging France	Prohance	Gadoteridol 4189.5mg/15 MI	Solution for injection	Intravenous use
France	Bracco Imaging France	Prohance	Gadoteridol 5586mg/20 MI	Solution for injection	Intravenous use
France	Bracco Imaging France	Prohance	Gadoteridol 2793mg/10 MI	Solution for injection in pre-filled syringe	Intravenous use
France	Bracco Imaging France	Prohance	Gadoteridol 4189.5mg/15 MI	Solution for injection in pre-filled syringe	Intravenous use
France	Bracco Imaging France	Prohance	Gadoteridol 4748.1mg/17 MI	Solution for injection in pre-filled syringe	Intravenous use
France	Ge Healthcare Sas	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
France	Ge Healthcare Sas	Omniscan	Gadodiamide 287mg/MI	Solution for injection in pre-filled syringe	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
France	Guerbet	Artirem	Gadoteric Acid 1.397mg/MI	Solution for injection	Intraarticular use
France	Guerbet	Dotarem	Gadoteric Acid 27.932g/100 MI	Solution for injection	Intravenous use
France	Guerbet	Dotarem	Gadoteric Acid 27.932g/100 MI	Solution for injection in pre-filled syringe	Intravenous use
Germany	Agfa Healthcare Imaging Agents Gmbh	Dotagita	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Germany	Agfa Healthcare Imaging Agents Gmbh	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Germany	B.E.Imaging.Gmbh	Magnevision	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Germany	B.E.Imaging.Gmbh	Magnevision B.E.	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Germany	Bayer Vital Gmbh	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Germany	Bayer Vital Gmbh	Magnevist	Gadopentetate Dimeglumine 1.88mg/MI	Solution for injection	Intraarticular use
Germany	Bayer Vital Gmbh	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Germany	Bayer Vital Gmbh	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Germany	Bracco Imaging Deutschland GmbH	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Germany	Bracco Imaging Deutschland GmbH	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Germany	Eurocontrast GmbH	Dotarem Dsf	Gadoteric Acid 0.5mmol/MI	Solution for injection	Intravenous use
Germany	Eurocontrast GmbH	Dotarem Fsp	Gadoteric Acid 0.5mmol/MI	Solution for injection in pre-filled syringe	Intravenous use
Germany	Eurocontrast GmbH	Gadovist Dsf	Gadobutrol 1mmol/MI	Solution for injection	Intravenous use
Germany	Eurocontrast GmbH	Gadovist Fsp	Gadobutrol 1mmol/MI	Solution for injection	Intravenous use
Germany	Eurocontrast GmbH	Magnegita	Gadopentetate Dimeglumine 500µmol/MI	Solution for injection	Intravenous use
Germany	Eurocontrast GmbH	Magnevist	Gadopentetate Dimeglumine 0.5mmol/MI	Solution for injection	Intravenous use
Germany	Eurocontrast GmbH	Multihance	Gadobenic Acid 0.5 Molar / MI	Solution for injection	Intravenous use
Germany	Eurocontrast GmbH	Omniscan 0,5 Mmol/MI	Gadodiamide 0.5mmol/MI	Solution for injection	Intravenous use
Germany	Eurocontrast GmbH	Omniscan 0,5 Mmol/MI	Gadodiamide 0.5mmol/MI	Solution for injection in pre-filled syringe	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Germany	Eurocontrast Gmbh	Primovist 0,25 Mmol/MI Injektionslösung	Gadoxetic Acid, Disodium 0.25mmol/MI	Solution for injection in pre-filled syringe	Intravenous use
Germany	Eurocontrast Gmbh	Prohance	Gadoteridol 0.5 Molar / MI	Solution for injection	Intravenous use
Germany	Ge Healthcare Buchler Gmbh & Co. Kg	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Germany	Ge Healthcare Buchler Gmbh & Co. Kg	Omniscan	Gadodiamide 287mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Germany	Guerbet	Artirem	Gadoteric Acid 1.397mg/MI	Solution for injection	Intraarticular use
Germany	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Germany	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Germany	Guerbet	Dotaspin	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Germany	Guerbet	Dotaspin	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Germany	Jenapharm Gmbh & Co Kg	Dotagraf	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Germany	Jenapharm Gmbh & Co Kg	Magnograf	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Germany	M.C.S. Conpharm Gmbh	Gadopentat	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Germany	Medithek Gmbh	Gadocon	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Germany	Medithek Gmbh	Gadopent	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Germany	Medithek Gmbh	Gadothek	Gadopentetate Dimeglumine 500µmol/MI	Solution for injection	Intravenous use
Germany	Radco-Imaging Gmbh	Gadolan	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Germany	Radiomed Service Für Radiologische Großpraxen Gmbh	Gadopur	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Germany	Sanochemia Diagnostics Deutschland Gmbh	Mr-Lux	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Germany	Sanochemia Pharmazeutika Ag	Cyclolux	Gadoteric Acid 0.5mmol/MI	Solution for injection	Intravenous use
Germany	Sanochemia Pharmazeutika Ag	Gadoteric Acid Gadotersäure Sanochemia 0,5 Mmol/MI Injektionslösung	Gadoteric Acid 0.5 Milli Molar / MI	Solution for injection	Intravenous use
Germany	Sanochemia Pharmazeutika Ag	Gadotersäure Sanochemia	Gadoteric Acid 0.5 Milli Molar / MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Germany	Sanochemia Pharmazeutika Ag	Gadotersäure Sanochemia	Gadoteric Acid 0.5mmol/MI	Solution for injection	Intravenous use
Germany	Sanochemia Pharmazeutika Ag	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Greece	Bayer Hellas Sa	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Greece	Bayer Hellas Sa	Gadovist Pfs	Gadobutrol 604.72mg/MI	Solution for injection in cartridge solution for injection in pre-filled syringe	Intravenous use
Greece	Bayer Hellas Sa	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Greece	Bayer Hellas Sa	Primovist Pfs	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Greece	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Greece	Ge Healthcare Ae	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Greece	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Greece	Vianex S.A.	Magnetolux	Gadopentetate Dimeglumine 500µmol/MI	Ενεσιμο διαλυμα	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Hungary	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Hungary	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Hungary	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Hungary	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 10580mg/20 MI	Solution for injection	Intravenous use
Hungary	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 2645mg/5 MI	Solution for injection	Intravenous use
Hungary	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 5290mg/10 MI	Solution for injection	Intravenous use
Hungary	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 7935mg/15 MI	Solution for injection	Intravenous use
Hungary	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 10580mg/20 MI	Solution for injection in pre-filled syringe	Intravenous use
Hungary	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 5290mg/10 MI	Solution for injection in pre-filled syringe	Intravenous use
Hungary	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 7935mg/15 MI	Solution for injection in pre-filled syringe	Intravenous use
Hungary	Ge Healthcare As	Omniscan	Gadodiamide 14.35g/50 MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Hungary	Ge Healthcare As	Omniscan	Gadodiamide 2.87g/10 MI	Solution for injection	Intravenous use
Hungary	Ge Healthcare As	Omniscan	Gadodiamide 4.31g/15 MI	Solution for injection	Intravenous use
Hungary	Ge Healthcare As	Omniscan	Gadodiamide 5.74g/20 MI	Solution for injection	Intravenous use
Hungary	Ge Healthcare As	Omniscan	Gadodiamide 5.74mol/15 MI	Solution for injection	Intravenous use
Hungary	Guerbet	Dotarem	Gadoteric Acid 27.932g/100 MI	Solution for injection	Intravenous use
Hungary	Guerbet	Dotarem	Gadoteric Acid 27.932mg/100 MI	Solution for injection	Intravenous use
Hungary	Sanochemia Pharmazeutika Ag	Cyclolux	Gadoteric Acid 0.5mmol/MI	Solution for injection	Intravenous use
Hungary	Sanochemia Pharmazeutika Ag	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Iceland	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Iceland	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	Solution for injection	Intraarticular use
Iceland	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Iceland	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Iceland	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Iceland	Mallinckrodt Deutschland Gmbh	Optimark	Gadoversetamide 330.9mg/MI	Solution for injection	Intravenous use
Iceland	Mallinckrodt Deutschland Gmbh	Optimark	Gadoversetamide 330.9mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Ireland	Bayer Ltd	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Ireland	Bayer Ltd	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Ireland	Bayer Ltd	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Ireland	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Ireland	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Ireland	Bracco International Bv	Prohance	Gadoteridol 2793mg/10 MI	Solution for injection	Intravenous use
Ireland	Bracco International Bv	Prohance	Gadoteridol 4189.5mg/15 MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Ireland	Bracco International Bv	Prohance	Gadoteridol 5586mg/20 MI	Solution for injection	Intravenous use
Ireland	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Ireland	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Ireland	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Italy	Agfa Healthcare Imaging Agents Gmbh	Dotagita	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Italy	Agfa Healthcare Imaging Agents Gmbh	Dotamulti	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Italy	Agfa Healthcare Imaging Agents Gmbh	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Italy	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 1.88mg/MI	Solution for injection	Intraarticular use
Italy	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469mg/MI	Solution for injection/infusion	Intravenous use
Italy	Bayer Spa	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Italy	Bayer Spa	Magnograf	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Italy	Bayer Spa	Magnograf	Gadopentetate Dimeglumine 469mg/MI	Solution for injection/infusion	Intravenous use
Italy	Bayer Spa	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Italy	Bracco Imaging Italia Srl	Prohance	Gadoteridol 1396.5mg/5 MI	Solution for injection	Intravenous use
Italy	Bracco Imaging Italia Srl	Prohance	Gadoteridol 13965mg/50 MI	Solution for injection	Intravenous use
Italy	Bracco Imaging Italia Srl	Prohance	Gadoteridol 2793mg/10 MI	Solution for injection	Intravenous use
Italy	Bracco Imaging Italia Srl	Prohance	Gadoteridol 4189.5mg/15 MI	Solution for injection	Intravenous use
Italy	Bracco Imaging Italia Srl	Prohance	Gadoteridol 4748.1mg/17 MI	Solution for injection	Intravenous use
Italy	Bracco Imaging Italia Srl	Prohance	Gadoteridol 5586mg/20 MI	Solution for injection	Intravenous use
Italy	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 10580mg/20 MI	Solution for injection	Intravenous use
Italy	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 2645mg/5 MI	Solution for injection	Intravenous use
Italy	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 5290mg/10 MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Italy	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 7935mg/15 MI	Solution for injection	Intravenous use
Italy	Ge Healthcare S.R.L.	Omniscan	Gadodiamide 0.5mmol/MI	Solution for injection	Intravenous use
Italy	Guerbet	Dotarem	Gadoteric Acid 0.0025mmol/MI	Solution for injection	Intraarticular use
Italy	Guerbet	Dotarem	Gadoteric Acid 27.932g/100 MI	Solution for injection	Intravenous use
Italy	Sanochemia Pharmazeutika Ag	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Latvia	Agfa Healthcare Imaging Agents Gmbh	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Latvia	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Latvia	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Latvia	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Latvia	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Latvia	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Latvia	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Lithuania	Agfa Healthcare Imaging Agents Gmbh	Dotagita	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Lithuania	Agfa Healthcare Imaging Agents Gmbh	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Lithuania	Agfa Healthcare Imaging Agents Gmbh	Magnegita	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Lithuania	Agfa Healthcare Imaging Agents Gmbh	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection/infusion	Intravenous use
Lithuania	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Lithuania	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Lithuania	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Lithuania	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Lithuania	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Lithuania	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Luxembourg	Bayer Sa Nv	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Luxembourg	Bayer Sa Nv	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Luxembourg	Bayer Sa Nv	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Luxembourg	Bracco Imaging Deutschland Gmbh	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Luxembourg	Bracco Imaging Deutschland Gmbh	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Luxembourg	Ge Healthcare Bvba	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Luxembourg	Guerbet	Artirem	Gadoteric Acid 1.397mg/MI	Solution for injection	Intraarticular use
Luxembourg	Guerbet	Dotarem	Meglumine Gadoterate 0.5mmol/MI	Solution for injection	Intravenous use
Luxembourg	Medithek Gmbh	Gadocon	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Luxembourg	Medithek Gmbh	Gadopent	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Luxembourg	Medithek Gmbh	Gadothek	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Malta	Bayer Plc	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Malta	Bayer Plc	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Malta	Bayer Plc	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Malta	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Netherlands	Bayer Bv	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Netherlands	Bayer Bv	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection in cartridge solution for injection in pre-filled syringe	Intravenous use
Netherlands	Bayer Bv	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Netherlands	Bracco Imaging Deutschland Gmbh	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Netherlands	Bracco Imaging Deutschland Gmbh	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Netherlands	Ge Healthcare B.V.	Omniscan	Gadodiamide 2.87g/10 MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Netherlands	Ge Healthcare B.V.	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Netherlands	Ge Healthcare B.V.	Omniscan	Gadodiamide 4.305g/15 MI	Solution for injection	Intravenous use
Netherlands	Ge Healthcare B.V.	Omniscan	Gadodiamide 5.74g/20 MI	Solution for injection	Intravenous use
Netherlands	Guerbet	Gadoteerzuur Guerbet	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Netherlands	Guerbet	Gadoteerzuur Guerbet	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Netherlands	Guerbet Nederland Bv	Artirem	Gadoteric Acid 1.397mg/MI	Solution for injection in pre-filled syringe	Intraarticular use
Netherlands	Guerbet Nederland Bv	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Netherlands	Guerbet Nederland Bv	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Norway	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Norway	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	Solution for injection	Intraarticular use
Norway	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Norway	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Norway	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Norway	Bracco International Bv	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Norway	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Norway	Guerbet	Dotarem	Gadoteric Acid 279.3mg/MI	Solution for injection	Intravenous use
Norway	Mallinckrodt Deutschland Gmbh	Optimark	Gadoversetamide 330.9mg/MI	Solution for injection	Intravenous use
Norway	Mallinckrodt Deutschland Gmbh	Optimark	Gadoversetamide 330.9mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Poland	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Poland	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Poland	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Poland	Bracco Imaging Deutschland Gmbh	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Poland	Bracco Imaging Deutschland GmbH	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Poland	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Poland	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Poland	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Poland	Sanochemia Pharmazeutika Ag	Cyclolux	Gadoteric Acid 0.5 Milli Molar / MI	Solution for injection	Intravenous use
Poland	Sanochemia Pharmazeutika Ag	Cyclolux Multidose	Gadoteric Acid 0.5mmol/MI	Solution for injection	Intravenous use
Portugal	A. Martins & Fernandes, S.A.	Dotarem	Meglumine Gadoterate 377mg/MI	Solution for injection	Intravenous use
Portugal	Bayer Portugal Sa	Magnevist	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Portugal	Bayer Portugal Sa	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Portugal	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 10580mg/20 MI	Solution for injection	Intravenous use
Portugal	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 2645mg/5 MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Portugal	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 5290mg/10 MI	Solution for injection	Intravenous use
Portugal	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 7935mg/15 MI	Solution for injection	Intravenous use
Portugal	Lusal Lda	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Portugal	Lusal Lda	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection in cartridge	Intravenous use
Portugal	Lusal Lda	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Portugal	Satis-Radioisótopos E Protecções Contra Sobretensões Eléctricas Unipessoal, Lda	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Romania	Agfa Healthcare Imaging Agents GmbH	Dotagita	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Romania	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection/infusion	Intravenous use
Romania	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Romania	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Romania	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Romania	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 10580mg/20 MI	Solution for injection	Intravenous use
Romania	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 2645mg/5 MI	Solution for injection	Intravenous use
Romania	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 5290mg/10 MI	Solution for injection	Intravenous use
Romania	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 7935mg/15 MI	Solution for injection	Intravenous use
Romania	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Romania	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Romania	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Romania	Sanochemia Pharmazeutika Ag	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Slovakia	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection/infusion	Intravenous use
Slovakia	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Slovakia	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Slovakia	Bracco Imaging Deutschland Gmbh	Prohance	Gadoteridol 1396.5mg/5 MI	Solution for injection	Intravenous use
Slovakia	Bracco Imaging Deutschland Gmbh	Prohance	Gadoteridol 2793mg/10 MI	Solution for injection	Intravenous use
Slovakia	Bracco Imaging Deutschland Gmbh	Prohance	Gadoteridol 4189.5mg/15 MI	Solution for injection	Intravenous use
Slovakia	Bracco Imaging Deutschland Gmbh	Prohance	Gadoteridol 4748.1mg/17 MI	Solution for injection	Intravenous use
Slovakia	Bracco Imaging Deutschland Gmbh	Prohance	Gadoteridol 5586mg/20 MI	Solution for injection	Intravenous use
Slovakia	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Slovakia	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Slovakia	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Slovakia	Sanochemia Pharmazeutika Ag	Cyclolux	Gadoteric Acid 0.5mmol/MI	Solution for injection	Intravenous use
Slovakia	Sanochemia Pharmazeutika Ag	Cyclolux Multi	Gadoteric Acid 0.5 Milli Molar / MI	Solution for injection	Intravenous use
Slovakia	Sanochemia Pharmazeutika Ag	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Slovenia	Agfa Healthcare Imaging Agents Gmbh	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection/infusion	Intravenous use
Slovenia	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Slovenia	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Slovenia	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Slovenia	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 10580mg/20 MI	Solution for injection	Intravenous use
Slovenia	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 2645mg/5 MI	Solution for injection	Intravenous use
Slovenia	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 5290mg/10 MI	Solution for injection	Intravenous use
Slovenia	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 7935mg/15 MI	Solution for injection	Intravenous use
Slovenia	Emporio Medical D.O.O.	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Slovenia	Ge Healthcare As	Omniscan	Gadodiamide 1.44g/5 MI	Solution for injection	Intravenous use
Slovenia	Ge Healthcare As	Omniscan	Gadodiamide 2.87g/10 MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Slovenia	Ge Healthcare As	Omniscan	Gadodiamide 4.31g/15 MI	Solution for injection	Intravenous use
Slovenia	Ge Healthcare As	Omniscan	Gadodiamide 5.74g/20 MI	Solution for injection	Intravenous use
Spain	Agfa Healthcare Imaging Agents Gmbh	Dotagita	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Spain	Bayer Hispania SI	Dotagraf	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
Spain	Bayer Hispania SI	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Spain	Bayer Hispania SI	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Spain	Bayer Hispania SI	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Spain	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Spain	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Spain	Bracco International Bv	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
Spain	Ge Healthcare Bio-Sciences, S.A.U.	Omniscan	Gadodiamide 287mg/MI	Solution for injection in pre-filled syringe	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Spain	Guerbet	Dotarem	Meglumine Gadoterate 376.4mg/MI	Solution for injection	Intravenous use
Spain	Guerbet	Dotarem	Meglumine Gadoterate 376.4mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Spain	Sanochemia Pharmazeutika Ag	Cyclolux	Gadoteric Acid 0.5 Milli Molar / MI	Solution for injection	Intravenous use
Spain	Sanochemia Pharmazeutika Ag	Cyclolux Rep	Gadoteric Acid 0.5 Milli Molar / MI	Solution for injection	Intravenous use
Spain	Sanochemia Pharmazeutika Ag	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use
Sweden	Bayer Pharma Ag	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
Sweden	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 1.88mg/MI	Solution for injection	Intraarticular use
Sweden	Bayer Pharma Ag	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
Sweden	Bayer Pharma Ag	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
Sweden	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
Sweden	Bracco International Bv	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
Sweden	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
Sweden	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection in pre-filled syringe	Intravenous use
Sweden	Guerbet	Dotarem	Gadoteric Acid 279.3mg/MI	Solution for injection	Intravenous use
United Kingdom	Agfa Healthcare Imaging Agents Gmbh	Dotagita	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
United Kingdom	Agfa Healthcare Imaging Agents Gmbh	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
United Kingdom	Bayer Plc	Gadovist	Gadobutrol 604.72mg/MI	Solution for injection	Intravenous use
United Kingdom	Bayer Plc	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	Solution for injection	Intraarticular use
United Kingdom	Bayer Plc	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	Solution for injection	Intravenous use
United Kingdom	Bayer Plc	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	Solution for injection	Intravenous use
United Kingdom	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection	Intravenous use
United Kingdom	Bracco Imaging S.P.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	Solution for injection in pre-filled syringe	Intravenous use

Member state	Marketing Authorisation Holder	Short name of the Medicinal Product	Active substance + Strength	Pharmaceutical form	Route of administration
United Kingdom	Bracco International Bv	Prohance	Gadoteridol 279.3mg/MI	Solution for injection	Intravenous use
United Kingdom	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Injection	Intravenous use
United Kingdom	Ge Healthcare As	Omniscan	Gadodiamide 287mg/MI	Solution for injection	Intravenous use
United Kingdom	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection	Intravenous use
United Kingdom	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	Solution for injection in pre-filled syringe	Intravenous use
United Kingdom	Sanochemia Pharmazeutika Ag	Cyclolux	Gadoteric Acid 0.5mmol/MI	Solution for injection	Intravenous use
United Kingdom	Sanochemia Pharmazeutika Ag	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	Solution for injection	Intravenous use

Centrally authorised medicinal products

MA (EU) number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Immediate Packaging	Content (concentration)	Pack size
EU/1/07/398/001	Optimark	500 micromol/ml	Solution for injection	Intravenous use	vial (glass)	10 ml	1 vial
EU/1/07/398/002	Optimark	500 micromol/ml	Solution for injection	Intravenous use	vial (glass)	10 ml	10 vials
EU/1/07/398/003	Optimark	500 micromol/ml	Solution for injection	Intravenous use	vial (glass)	15 ml	1 vial
EU/1/07/398/004	Optimark	500 micromol/ml	Solution for injection	Intravenous use	vial (glass)	15 ml	10 vials
EU/1/07/398/005	Optimark	500 micromol/ml	Solution for injection	Intravenous use	vial (glass)	20 ml	1 vial
EU/1/07/398/006	Optimark	500 micromol/ml	Solution for injection	Intravenous use	vial (glass)	20 ml	10 vials
EU/1/07/398/007	Optimark	500 micromol/ml	Solution for injection	Intravenous use	pre-filled syringe (PP)	10 ml	1 pre-filled syringe
EU/1/07/398/008	Optimark	500 micromol/ml	Solution for injection	Intravenous use	pre-filled syringe (PP)	10 ml	10 pre-filled syringes

MA (EU) number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Immediate Packaging	Content (concentration)	Pack size
EU/1/07/398/009	Optimark	500 micromol/ml	Solution for injection	Intravenous use	pre-filled syringe (PP)	15 ml	1 pre-filled syringe
EU/1/07/398/010	Optimark	500 micromol/ml	Solution for injection	Intravenous use	pre-filled syringe (PP)	15 ml	10 pre-filled syringes
EU/1/07/398/011	Optimark	500 micromol/ml	Solution for injection	Intravenous use	pre-filled syringe (PP)	20 ml	1 pre-filled syringe
EU/1/07/398/012	Optimark	500 micromol/ml	Solution for injection	Intravenous use	pre-filled syringe (PP)	20 ml	10 pre-filled syringes
EU/1/07/398/013	Optimark	500 micromol/ml	Solution for injection	Intravenous use	pre-filled syringe (PP)	30 ml	1 pre-filled syringe
EU/1/07/398/014	Optimark	500 micromol/ml	Solution for injection	Intravenous use	pre-filled syringe (PP)	30 ml	10 pre-filled syringes