

Annex I

List of nationally authorised medicinal products

Annex IA – medicinal products containing intravenous gadobenic acid, gadobutrol, gadoteric acid, gadoteridol, gadoxetic acid and intra-articular gadopentetic acid and intra-articular gadoteric acid

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Bayer Austria GmbH	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	solution for injection	intra-aintra-articular use
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	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use
Austria	Bracco Imaging S.p.A.	Prohance	Gadoteridol 279.3mg/MI	solution for injection	intravenous use
Austria	Guerbet	Artirem	Gadoteric Acid 1.397mg/MI	solution for injection	intra-articular use
Austria	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	solution for injection	intravenous use
Austria	Sanochemia Pharmazeutika AG	Cyclolux	Gadoteric Acid 0.5mmol/MI	solution for injection	intravenous use
Austria	Bracco Imaging S.p.A.	Multihance	Gadobenate Dimeglumine 529mg/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

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Belgium	Bayer SA NV	Gadovist	Gadobutrol 604.72mg/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	Prohance	Gadoteridol 279.3mg/MI	solution for injection	intravenous use
Belgium	Guerbet	Artirem	Gadoteric Acid 1.397mg/MI	solution for injection	intra-articular use
Belgium	Guerbet	Dotarem	Meglumine Gadoterate 0.5mmol/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
Bulgaria	Bayer Pharma AG	гадовист	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Bulgaria	Bayer Pharma AG	примовист	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use
Bulgaria	Guerbet	дотарем	Gadoteric Acid 279.32mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Bulgaria	Guerbet	дотарем	Gadoteric Acid 279.32mg/MI	solution for injection in pre-filled syringe	intravenous use
Croatia	Bayer d.o.o.	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Croatia	Bayer d.o.o.	Primovist	Gadoxetic Acid, Disodium 181.43mg/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
Croatia	Bracco Imaging S.p.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	solution for injection	intravenous use
Cyprus	Bayer Hellas SA	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
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
Czech Republic	Bayer AG	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Czech Republic	Bayer AG	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use
Czech Republic	Bracco Imaging Deutschland GmbH	Prohance	Gadoteridol 279.3mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Czech Republic	Bracco Imaging Deutschland GmbH	Prohance	Gadoteridol 279.3mg/MI	solution for injection in pre-filled syringe	intravenous use
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
Czech Republic	Bracco Imaging Deutschland GmbH	Multihance	Gadobenate Dimeglumine 529mg/MI	solution for injection	intravenous use
Denmark	Bayer AB	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	solution for injection	intra-articular use
Denmark	Bayer AB	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Denmark	Bracco International BV	Prohance	Gadoteridol 279.3mg/MI	solution for injection	intravenous use
Denmark	Guerbet	Dotarem Arthro	Gadoteric Acid 1.397mg/MI	solution for injection in pre-filled syringe	intra-articular 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
Denmark	Bracco Imaging S.p.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	solution for injection	intravenous use
Estonia	Agfa Healthcare Imaging Agents GmbH	Dotagita	Gadoteric Acid 279.32mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Estonia	Bayer AG	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Estonia	Bayer AG	Primovist	Gadoxetic Acid, Disodium 181.43mg/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	Primovist	Gadoxetic Acid, Disodium 181.43mg/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
Finland	Bracco Imaging S.p.A.	Multihance	Gadobenate Dimeglumine 529mg/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 SA NV	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	solution for injection in pre-filled syringe	intra-articular use
France	Bayer Healthcare	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
France	Bracco Imaging France	Prohance	Gadoteridol 1396.5mg/5 MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
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	Guerbet	Artirem	Gadoteric Acid 1.397mg/MI	solution for injection	intra-articular 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
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 EU/EEA	Marketing authorisation holder	Invented name	INN + 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
Germany	Agfa Healthcare Imaging Agents GmbH	Dotagita	Gadoteric Acid 279.32mg/MI	solution for injection	intravenous use
Germany	Bayer Vital GmbH	Magnevist	Gadopentetate Dimeglumine 1.88mg/MI	solution for injection	intra-articular use
Germany	Bayer Vital GmbH	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Germany	Bayer Vital GmbH	Primovist	Gadoxetic Acid, Disodium 181.43mg/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	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	Prohance	Gadoteridol 0.5 Molar / 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

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + 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	Guerbet	Artirem	Gadoteric Acid 1.397mg/MI	solution for injection	intra-articular use
Germany	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	solution for injection	intravenous use
Germany	Guerbet	Dotaspin	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 in pre-filled syringe	intravenous use
Germany	Jenapharm GmbH & Co Kg	Dotagraf	Gadoteric Acid 279.32mg/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
Germany	Sanochemia Pharmazeutika AG	Gadotersäure Sanochemia	Gadoteric Acid 0.5mmol/MI	solution for injection	intravenous use
Germany	Bracco Imaging Deutschland GmbH	Multihance	Gadobenate Dimeglumine 529mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Germany	Eurocontrast GmbH	Multihance	Gadobenic Acid 0.5 Molar / Ml	solution for injection	intravenous use
Greece	Bayer Hellas SA	Gadovist	Gadobutrol 604.72mg/Ml	solution for injection	intravenous use
Greece	Bayer Hellas SA	Gadovist Pfs	Gadobutrol 604.72mg/Ml	solution for injection in cartridge solution for injection in pre-filled syringe	intravenous use
Greece	Bayer Hellas SA	Primovist Pfs	Gadoxetic Acid, Disodium 181.43mg/Ml	solution for injection in pre-filled syringe	intravenous use
Greece	Guerbet	Dotarem	Gadoteric Acid 279.32mg/Ml	solution for injection	intravenous use
Greece	Bracco Imaging S.p.A.	Multihance	Gadobenate Dimeglumine 529mg/Ml	solution for injection	intravenous use
Hungary	Bayer AG	Gadovist	Gadobutrol 604.72mg/Ml	solution for injection	intravenous use
Hungary	Bayer AG	Primovist	Gadoxetic Acid, Disodium 181.43mg/Ml	solution for injection	intravenous use
Hungary	Guerbet	Dotarem	Gadoteric Acid 27.932g/100 Ml	solution for injection	intravenous use
Hungary	Guerbet	Dotarem	Gadoteric Acid 27.932mg/100 Ml	solution for injection	intravenous use
Hungary	Sanochemia Pharmazeutika AG	Cyclolux	Gadoteric Acid 0.5mmol/Ml	solution for injection	intravenous use
Hungary	Bracco Imaging S.p.A.	Multihance	Gadobenate Dimeglumine 10580mg/20 Ml	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
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
Iceland	Bayer Pharma AG	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	solution for injection	intra-articular use
Iceland	Bayer AB	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Ireland	Bayer Ltd	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Ireland	Bayer Ltd	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use
Ireland	Bracco International BV	Prohance	Gadoteridol 2793mg/10 MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Ireland	Bracco International BV	Prohance	Gadoteridol 4189.5mg/15 MI	solution for injection	intravenous use
Ireland	Bracco International BV	Prohance	Gadoteridol 5586mg/20 MI	solution for injection	intravenous use
Ireland	Guerbet	Dotarem	Gadoteric Acid 279.32mg/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
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	Bayer Pharma AG	Magnevist	Gadopentetate Dimeglumine 1.88mg/MI	solution for injection	intra-articular use
Italy	Bayer S.p.A.	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Italy	Bayer S.p.A.	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

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
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	Guerbet	Dotarem	Gadoteric Acid 0.0025mmol/MI	solution for injection	intra-articular use
Italy	Guerbet	Dotarem	Gadoteric Acid 27.932g/100 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
Italy	Bracco Imaging S.p.A.	Multihance	Gadobenate Dimeglumine 7935mg/15 MI	solution for injection	intravenous use
Latvia	Bayer Pharma AG	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Latvia	Bayer Pharma AG	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use
Latvia	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + 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	Bayer Pharma AG	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Lithuania	Bayer Pharma AG	Primovist	Gadoxetic Acid, Disodium 181.43mg/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
Luxembourg	Bayer SA NV	Gadovist	Gadobutrol 604.72mg/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	Prohance	Gadoteridol 279.3mg/MI	solution for injection	intravenous use
Luxembourg	Guerbet	Artirem	Gadoteric Acid 1.397mg/MI	solution for injection	intra-articular use
Luxembourg	Guerbet	Dotarem	Meglumine Gadoterate 0.5mmol/MI	solution for injection	intravenous use
Luxembourg	Bracco Imaging Deutschland GmbH	Multihance	Gadobenate Dimeglumine 529mg/MI	solution for injection	intravenous use
Malta	Bayer PLC	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Malta	Bayer PLC	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Netherlands	Bayer BV	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Netherlands	Bayer BV	Primovist	Gadoxetic Acid, Disodium 181.43mg/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	Bracco Imaging Deutschland GmbH	Prohance	Gadoteridol 279.3mg/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	intra-articular 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
Netherlands	Bracco Imaging Deutschland GmbH	Multihance	Gadobenate Dimeglumine 529mg/MI	solution for injection	intravenous use
Norway	Bayer AB	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	solution for injection	intra-articular use
Norway	Bayer AB	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Norway	Bayer AB	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use
Norway	Bracco International BV	Prohance	Gadoteridol 279.3mg/MI	solution for injection	intravenous use
Norway	Guerbet	Dotarem	Gadoteric Acid 279.3mg/MI	solution for injection	intravenous use
Norway	Bracco Imaging S.p.A.	Multihance	Gadobenate Dimeglumine 529mg/MI	solution for injection	intravenous use
Poland	Bayer AG	Gadovist	Gadobutrol 604.72mg/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	Prohance	Gadoteridol 279.3mg/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
Poland	Bracco Imaging Deutschland GmbH	Multihance	Gadobenate Dimeglumine 529mg/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	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
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	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
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
Romania	Agfa Healthcare Imaging Agents GmbH	Dotagita	Gadoteric Acid 279.32mg/MI	solution for injection	intravenous use
Romania	Bayer Pharma AG	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Romania	Bayer Pharma AG	Primovist	Gadoxetic Acid, Disodium 181.43mg/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

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + 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
Slovakia	Bayer Pharma AG	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Slovakia	Bayer AG	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use
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	Guerbet	Dotarem	Gadoteric Acid 279.32mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
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
Slovenia	Bayer Pharma AG	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Slovenia	Bayer Pharma AG	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use
Slovenia	Emporio Medical d.o.o.	Dotarem	Gadoteric Acid 279.32mg/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
Spain	Agfa Healthcare Imaging Agents GmbH	Dotagita	Gadoteric Acid 279.32mg/MI	solution for injection	intravenous use
Spain	Bayer Hispania SL	Dotagraf	Gadoteric Acid 279.32mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Spain	Bayer Hispania SL	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Spain	Bayer Hispania SL	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use
Spain	Bracco International BV	Prohance	Gadoteridol 279.3mg/MI	solution for injection	intravenous use
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	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
Sweden	Bayer Pharma AG	Magnevist	Gadopentetate Dimeglumine 1.88mg/MI	solution for injection	intra-articular use
Sweden	Bayer AB	Gadovist	Gadobutrol 604.72mg/MI	solution for injection	intravenous use
Sweden	Bayer AB	Primovist	Gadoxetic Acid, Disodium 181.43mg/MI	solution for injection	intravenous use
Sweden	Bracco International BV	Prohance	Gadoteridol 279.3mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Sweden	Guerbet	Dotarem	Gadoteric Acid 279.3mg/MI	solution for injection	intravenous use
Sweden	Bracco Imaging S.p.A.	Multihance	Gadobenate Dimeglumine 529mg/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	Bayer PLC	Magnevist	Gadopentetate Dimeglumine 1.876mg/MI	solution for injection	intra-articular use
United Kingdom	Bayer PLC	Gadovist	Gadobutrol 604.72mg/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 International BV	Prohance	Gadoteridol 279.3mg/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	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

Annex IB –medicinal products containing gadodiamide, gadopentetic acid and gadoversetamide for intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Bayer Austria GmbH	Magnevist	Gadopentetate Dimeglumine 469mg/MI	solution for injection	intravenous use
Austria	GE Healthcare Handels GmbH	Omniscan	Gadodiamide 287mg/MI	solution for injection	intravenous use
Austria	Sanochemia Pharmazeutika AG	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	solution for injection	intravenous use
Belgium	Bayer SA NV	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Belgium	GE Healthcare Bvba	Omniscan	Gadodiamide 287mg/MI	solution for injection	intravenous use
Bulgaria	Bayer Pharma AG	магневист	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Bulgaria	GE Healthcare AS	омнискен	Gadodiamide 287mg/MI	solution for injection	intravenous use
Bulgaria	Sanochemia Pharmazeutika AG	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	solution for injection	intravenous use
Croatia	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Croatia	Bayer d.o.o.	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Croatia	GE Healthcare d.o.o.	Omniscan	Gadodiamide 287mg/MI	solution for injection	intravenous use
Cyprus	Bayer Hellas SA	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Cyprus	Phadisco Ltd	Omniscan	Gadodiamide 287mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Czech Republic	Bayer AG	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Czech Republic	GE Healthcare AS	Omniscan	Gadodiamide 287mg/MI	solution for injection	intravenous use
Denmark	Bayer Pharma AG	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Denmark	GE Healthcare AS	Omniscan	Gadodiamide 0.5mmol/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 AG	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Estonia	GE Healthcare AS	Omniscan	Gadodiamide 287mg/MI	solution for injection	intravenous use
Finland	Bayer Oy	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
France	Bayer Healthcare	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	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
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

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Germany	Bayer Vital GmbH	Magnevist	Gadopentetate Dimeglumine 469.01mg/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	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
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	Jenapharm GmbH & Co Kg	Magnograf	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
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

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
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	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	solution for injection	intravenous use
Greece	Bayer Hellas SA	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Greece	GE Healthcare Ae	Omniscan	Gadodiamide 287mg/MI	solution for injection	intravenous use
Greece	Vianex S.A.	Magnetolux	Gadopentetate Dimeglumine 500µmol/MI	solution for injection	intravenous use
Hungary	Bayer AG	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Hungary	GE Healthcare AS	Omniscan	Gadodiamide 14.35g/50 MI	solution for injection	intravenous use
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	Sanochemia Pharmazeutika AG	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Iceland	Bayer AB	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
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	Magnevist	Gadopentetate Dimeglumine 469.01mg/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
Italy	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Italy	Bayer Pharma AG	Magnevist	Gadopentetate Dimeglumine 469mg/MI	solution for injection/infusion	intravenous use
Italy	Bayer S.p.A.	Magnograf	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Italy	Bayer S.p.A.	Magnograf	Gadopentetate Dimeglumine 469mg/MI	solution for injection/infusion	intravenous use
Italy	GE Healthcare S.R.L.	Omniscan	Gadodiamide 0.5mmol/MI	solution for injection	intravenous use
Italy	Sanochemia Pharmazeutika AG	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Latvia	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection	intravenous use
Latvia	Bayer Pharma AG	Magnevist	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection	intravenous use
Latvia	GE Healthcare AS	Omniscan	Gadodiamide 287mg/ML	solution for injection	intravenous use
Lithuania	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection	intravenous use
Lithuania	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469mg/ML	solution for injection	intravenous use
Lithuania	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection/infusion	intravenous use
Lithuania	Bayer Pharma AG	Magnevist	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection	intravenous use
Lithuania	GE Healthcare AS	Omniscan	Gadodiamide 287mg/ML	solution for injection	intravenous use
Luxembourg	Bayer SA NV	Magnevist	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection	intravenous use
Luxembourg	GE Healthcare Bvba	Omniscan	Gadodiamide 287mg/ML	solution for injection	intravenous use
Luxembourg	Medithek GmbH	Gadocon	Gadopentetate Dimeglumine 469mg/ML	solution for injection	intravenous use
Luxembourg	Medithek GmbH	Gadopent	Gadopentetate Dimeglumine 469mg/ML	solution for injection	intravenous use
Luxembourg	Medithek GmbH	Gadothek	Gadopentetate Dimeglumine 469mg/ML	solution for injection	intravenous use
Malta	Bayer PLC	Magnevist	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Malta	GE Healthcare AS	Omniscan	Gadodiamide 287mg/MI	solution for injection	intravenous use
Netherlands	GE Healthcare B.V.	Omniscan	Gadodiamide 2.87g/10 MI	solution for injection	intravenous use
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
Norway	Bayer Pharma AG	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Norway	GE Healthcare AS	Omniscan	Gadodiamide 287mg/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 AG	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
Poland	GE Healthcare AS	Omniscan	Gadodiamide 287mg/MI	solution for injection	intravenous use
Portugal	Bayer Portugal SA	Magnevist	Gadopentetate Dimeglumine 469mg/MI	solution for injection	intravenous use
Portugal	Satis-Radioisótopos E Protecções Contra Sobretensões Eléctricas Unipessoal, Lda	Omniscan	Gadodiamide 287mg/MI	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Romania	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection/infusion	intravenous use
Romania	Bayer Pharma AG	Magnevist	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection	intravenous use
Romania	GE Healthcare AS	Omniscan	Gadodiamide 287mg/ML	solution for injection	intravenous use
Romania	Sanochemia Pharmazeutika AG	Magnetolux	Gadopentetate Dimeglumine 469mg/ML	solution for injection	intravenous use
Slovakia	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection/infusion	intravenous use
Slovakia	GE Healthcare AS	Omniscan	Gadodiamide 287mg/ML	solution for injection	intravenous use
Slovakia	Sanochemia Pharmazeutika AG	Magnetolux	Gadopentetate Dimeglumine 469mg/ML	solution for injection	intravenous use
Slovenia	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection/infusion	intravenous use
Slovenia	Bayer Pharma AG	Magnevist	Gadopentetate Dimeglumine 469mg/ML	solution for injection	intravenous use
Slovenia	GE Healthcare AS	Omniscan	Gadodiamide 1.44g/5 ML	solution for injection	intravenous use
Slovenia	GE Healthcare AS	Omniscan	Gadodiamide 2.87g/10 ML	solution for injection	intravenous use
Slovenia	GE Healthcare AS	Omniscan	Gadodiamide 4.31g/15 ML	solution for injection	intravenous use
Slovenia	GE Healthcare AS	Omniscan	Gadodiamide 5.74g/20 ML	solution for injection	intravenous use
Spain	Bayer Hispania SL	Magnevist	Gadopentetate Dimeglumine 469.01mg/ML	solution for injection	intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Spain	GE Healthcare Bio- Sciences, S.A.U.	Omniscan	Gadodiamide 287mg/MI	solution for injection in pre-filled syringe	intravenous use
Spain	Sanochemia Pharmazeutika AG	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	solution for injection	intravenous use
Sweden	Bayer AB	Magnevist	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
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
United Kingdom	Agfa Healthcare Imaging Agents GmbH	Magnegita	Gadopentetate Dimeglumine 469.01mg/MI	solution for injection	intravenous use
United Kingdom	Bayer PLC	Magnevist	Gadopentetate Dimeglumine 469.01mg/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	Sanochemia Pharmazeutika AG	Magnetolux	Gadopentetate Dimeglumine 469mg/MI	solution for injection	intravenous use