



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2016
EMA/200877/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: gadoxetic acid disodium

Procedure no.: PSUSA/00001509/201504



Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Primovist		6317/2006/01-09	Bayer Pharma Ag	Romania
Primovist	SE/H/429/01-02	04-0408	Bayer Pharma Ag	Latvia
Primovist	SE/H/429/01-02	0442/06060013	Bayer Sa Nv	Luxembourg
Primovist	SE/H/429/01-02	11140	Bayer Pharma Ag	Poland
Primovist	SE/H/429/01-02	18929 \$ 18930	Bayer Pharma Ag	Sweden
Primovist	SE/H/429/01-02	19713	Bayer Hellas Sa	Cyprus
Primovist	SE/H/429/01-02	457504	Bayer Pharma Ag	Estonia
Primovist	SE/H/0429/001-002	48/177/04-C \$ 48/178/04-C	Bayer Pharma Ag	Czech Republic
Primovist	SE/H/429/01-02	5320486 \$ 5320585 \$ 5320684 \$ 5320783 \$ 5320882 \$ 5320981 \$ 5321088 \$ 5321187 \$ 5321286 \$ 5321385 \$ 5321484 \$ 5321583 \$ 5321682 \$ 5321781 \$ 5321880 \$ 5321989 \$ 5322086 \$ 5322185	Bayer Portugal Sa	Portugal

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Primovist	SE/H/429/01-02	5363-I-982/14	Bayer Pharma Ag	Slovenia
Primovist	SE/H/429/01-02	66.648	Bayer Hispania Sl	Spain
Primovist	SE/H/429/01-02	LT/1/04/0151/010 \$ LT/1/04/0151/011 \$ LT/1/04/0151/012 \$ LT/1/04/0151/013 \$ LT/1/04/0151/014 \$ LT/1/04/0151/015 \$ LT/1/04/0151/016 \$ LT/1/04/0151/017 \$ LT/1/04/0151/018	Bayer Pharma Ag	Lithuania
Primovist	SE/H/429/01-02	MA 513/03501 \$ MA 513/03502	Bayer Plc	Malta
Primovist	SE/H/429/01-02	PA 1410/21/1 \$ PA 1410/21/2	Bayer Ltd	Ireland
Primovist	SE/H/429/01-02	PL 00010-0555	Bayer Plc	United Kingdom
Primovist	SE/H/429/01-02	PL 00010/0554	Bayer Plc	United Kingdom
Primovist	SE/H/429/01-02	037025018 \$ 037025020 \$ 037025032 \$ 037025044 \$ 037025057 \$ 037025069 \$ 037025071 \$ 037025083 \$ 037025095 \$ 037025107 \$	Bayer Spa	Italy

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
		037025119 \$ 037025121 \$ 037025133 \$ 037025145 \$ 037025158 \$ 037025160 \$ 037025172 \$ 037025184		
Primovist	SE/H/429/01-02	19620 \$ 19621	Bayer Oy	Finland
Primovist	SE/H/429/01-02	04-2770 \$ 04-277	Bayer Pharma Ag	Norway
Primovist	SE/H/429/01-02	1-25757 \$ 1-25758	Bayer Austria Gmbh	Austria
Primovist	SE/H/429/01-02	48/0264/04-S \$ 48/0265/04-S	Bayer Pharma Ag	Slovakia
Primovist	SE/H/429/01-02	60470.00.00 \$ 60470.00.01	Bayer Vital Gmbh	Germany
Primovist	SE/H/429/01-02	BE281391 \$ BE281407 \$ BE281416 \$ BE281425 \$ BE281434 \$ BE281443	Bayer Sa Nv	Belgium
Primovist	SE/H/429/01-02	HR-H-392143167	Bayer D.o.o	Croatia
Primovist	SE/H/429/01-02	OGYI-T-9837/01 \$ OGYI-T-9837/02 \$ OGYI-T-9837/03 \$ OGYI-T- 9837/04 \$ OGYI-T-9837/05 \$ OGYI- T-9837/06 \$ OGYI-T-9837/07 \$ OGYI-T-9837/08 \$ OGYI-T-9837/09 \$ OGYI-T-9837/10 \$ OGYI-T-	Bayer Pharma Ag	Hungary

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
		9837/11 \$ OGYI-T-9837/12		
Primovist	SE/H/429/01-02	RVG 31393	Bayer Bv	Netherlands
Primovist	SE/H/429/01-02	2657902	Bayer Hellas Sa	Greece
ПРИМОВИСТ		20060034	Bayer Pharma Ag	Bulgaria