



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2016
EMA/40935/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: misoprostol (gynaecological indication - labor induction)

Procedure No.: PSUSA/00010353/201505



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	Legal basis
Misodel	SE/H/1224/001	021987	Ferring Pharmaceuticals A/S	Cyprus	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	12-9206	Ferring Legemidler As	Norway	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	13-0264	Ferring Lääkkeet Oy	Latvia	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	135351	Ferring Arzneimittel Ges.M.B.H.	Austria	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	21677	Ferring Gmbh	Poland	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	31017	Ferring Lääkkeet Oy	Finland	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	48411	Ferring Läkemedel Ab	Sweden	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	51419	Ferring Lægemidler A/S	Denmark	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	53822/19-6-2014	Ferring Hellas Mepe	Greece	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	54/123/14-C	Ferring Pharmaceuticals Cz S.R.O.	Czech Republic	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	586 168-1 OU 34009 586 168 1 5 586 169-8 OU 34009 586 169 8 3 586 170- 6 OU 34009 586 170 6 5	Ferring S.A.S.	France	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	6162/2014/01-02-03	Ferring Gmbh	Romania	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	78573	Ferring S.A.U.	Spain	Full application (Article 8(3) of Directive No 2001/83/EC)

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Misodel	SE/H/1224/001	81/0476/13-S	Ferring Léciva A.S.	Slovakia	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	87587.00.00	Ferring Arzneimittel GmbH	Germany	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	IS/1/13/092/01	Ferring Lægemedler A/S	Iceland	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	LT/1/13/3442/001 LT/1/13/3442/002 LT/1/13/3442/003	Ferring Lääkkeet Oy	Lithuania	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	OGYI-T-22575/01	Ferring Hungary Pharmaceutical Trading Co Ltd.	Hungary	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/001	RVG 112566	Ferring B.V.	Netherlands	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/01 SE/H/1224/01/DC	5616354 5616362 5616370	Ferring Portuguesa – Produtos Farmacêuticos, Sociedade Unipessoal, Lda.	Portugal	Full application (Article 8(3) of Directive No 2001/83/EC)
Misofar		69.682	Bial Industrial Farmacéutica, S.A.	Spain	Well-established use application (Article 10a of Directive No 2001/83/EC)
Mysodelle	SE/H/1224/001	042447019 042447021 042447033	Ferring S.P.A.	Italy	Full application (Article 8(3) of Directive No 2001/83/EC)
Mysodelle	SE/H/1224/001	5363-I-418/14 5363-I-419/14 5363-I-420/14	Ferring GmbH	Slovenia	Full application (Article 8(3) of Directive No 2001/83/EC)
Mysodelle	SE/H/1224/001	830713	Ferring Lääkkeet Oy	Estonia	Full application (Article 8(3) of Directive No 2001/83/EC)

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Mysodelle	SE/H/1224/001	BE445866	Ferring N.V.	Belgium	Full application (Article 8(3) of Directive No 2001/83/EC)
Mysodelle	SE/H/1224/001	2014090262 - 0759751; 0759765;0759779	Ferring N.V.	Luxembourg	Full application (Article 8(3) of Directive No 2001/83/EC)
Mysodelle	SE/H/1224/001	PA 1009/025/001	Ferring Ireland Ltd.	Ireland	Full application (Article 8(3) of Directive No 2001/83/EC)
Mysodelle	SE/H/1224/001	PL 03194/0112	Ferring Pharmaceuticals Ltd.	United Kingdom	Full application (Article 8(3) of Directive No 2001/83/EC)
Мизодел	SE/H/1224/001	20150034	Ferring Gmbh	Bulgaria	Full application (Article 8(3) of Directive No 2001/83/EC)
Misodel	SE/H/1224/01	N/A	FERRING PHARMACEUTICALS LTD.	Malta	Full application (Article 8(3) of Directive No 2001/83/EC)
Misofar		69683	Bial Industrial Farmacéutica, S.A.	Spain	Well-established use application (Article 10a of Directive No 2001/83/EC)