



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2015
EMA/589063/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance/combination of active substances: magnesium sulphate, sodium sulphate, potassium sulphate

Procedure No.: PSUSA/00010239/201502



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
Eziclen	FR/H/0511/001	13-0037	Ipsen Pharma	LV	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	21110	Ipsen Pharma	PL	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	5417/2013/01	Ipsen Pharma	RO	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	5573555	Ipsen Portugal Produtos Farmacêuticos, S.A.	PT	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	61/106/13-C	Ipsen Pharma	CZ	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	808713	Ipsen Pharma	EE	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	86203.00.00	Ipsen Pharma Gmbh	DE	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	BE434323	Ipsen N.V.	BE	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	BE434323	Ipsen N.V.	LU	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	FR/H/511/01/DC	Ipsen E.P.E.	GR	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	LT/1/13/3275/001	Ipsen Pharma	LT	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	77754	Ipsen Pharma Sa	ES	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	RVG 110863	Ipsen Farmaceutica B.V.	NL	Full application (Article 8(3) of Directive No 2001/83/EC)
Eziclen	FR/H/0511/001	BE434323	Ipsen N.V.	BE	Full application (Article 8(3) of Directive No 2001/83/EC)
Izinova	FR/H/0511/001	34009 269 952 9	Ipsen Pharma	FR	Full application (Article 8(3) of Directive No 2001/83/EC)
Izinova	FR/H/0511/001	41807013	Ipsen S.P.A.	IT	Full application (Article 8(3) of Directive No 2001/83/EC)
Izinova	FR/H/0511/001	PL 34926/0016	Ipsen Ltd	GB	Full application (Article 8(3) of Directive No

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