11 January 2024
EMA/PRAC/4056/2024
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): mifepristone / misoprostol

Procedure no.: PSUSA/00010378/202305

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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
Medabon pachet combinat de mifepristonă 200 mg comprimate şi misoprostol 4 x 0,2 mg comprimate vaginale.	NL/H/4796/001	10424/2017/01	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Medabon Combipack of Mifepristone 200 mg tablet and Misoprostol 4 x 0.2 mg vaginal tablets	NL/H/4796/001	PL 31750/0042	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	XI
Sunmedabon, Combinatieverpakking mifepriston 200 mg tablet en misoprostol 4 x 0,2 mg vaginale tabletten	NL/H/4796/001	RVG 106099	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL