



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 February 2016  
EMA/178486/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: misoprostol (gastrointestinal indication)

Procedure no.: PSUSA/00010291/201506



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Cyproston		1-19557	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Cytotec		BE134093	Continental Pharma, Inc.	Belgium
Cytotec		11978	Pfizer Aps	Denmark
Cytotec		10710	Pfizer Oy	Finland
Cytotec		NL 13893	Pfizer Holding France (S.C.A.)	France
Cytotec		40410/07/19-5-2008	Pfizer Hellas, A.E.	Greece
Cytotec		880109 (IS)	Pfizer Aps	Iceland
Cytotec		PA 822/118/1	Pfizer Healthcare Ireland	Ireland
Cytotec		026488015 \$ 026488027	Continental Pharma, Inc.	Italy
Misodex		027307014 \$ 027307026	Pfizer Italia S.R.L.	Italy
Cytotec		2007079404	Continental Pharma, Inc.	Luxembourg
Cytotec		RVG 13724	Pfizer B.V.	Netherlands

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Cytotec		8063	Pfizer As	Norway
Cytotec		R/2716	Pfizer Europe MA EEIG	Poland
Cytotec		1/68/84	Laboratórios Pfizer, Lda.	Portugal
Cytotec		58403	Pfizer, S.L.	Spain
Cytotec		11033	Pfizer Ab	Sweden
Cytotec		PL 00057/0956	Pfizer Limited	United Kingdom
Cytotec		AA505/05201	Pfizer Hellas S.A, Greece	Malta