

WHO List of Prequalified Medicinal Products

Printed from WHO prequalification web site (<http://www.who.int/prequal/>) on 2015-Mar-06 12:37 GMT.

For information about the listing of prequalified products and the alternative approval procedure, please see "General information" at http://www.who.int/prequal/info_general/notes_registry.htm.

Legend:

"+" means combination product, both fixed-dose combination (co-formulated) and co-packaged product (i.e. co-b blister)

[A+B] + C means A and B are in a fixed-dose formulation and C is co-packaged

"**" refers to products approved by both WHO Prequalification Programme and US FDA

USFDA1 - approved by USFDA; USFDA2 - tentatively approved by USFDA; EMEA Art 58 - approved by EMEA according to Article 58

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
RH	Desogestrel + Ethinylestradiol	Tablets 150?g + 30?g	Famy Care Ltd	Ahmedabad, Gujarat, India	PVC/PVdC/Alu blister in a sealed laminated film pouch 21	RH037 (a)	2013-Aug-14	
RH	Desogestrel + Ethinylestradiol	Tablets 150?g + 30?g	Lupin Ltd	Pitampur, Madhya Pradesh, India	Alu/PVC blister (available in a wallet) 28 (21 active and 7 placebo tablets per wallet further packed in a pouch). 3 pouches are packed in a carton	RH044 (a)	2013-Oct-21	
RH	Desogestrel + Ethinylestradiol	Tablets 150?g + 30?g	Famy Care Ltd	Ahmedabad, Gujarat, India	AL/PVC/PVDC blister 28 (21 active and 7 placebo tablets per blister in a sealed laminated film in pouch). 1 or 3 pouches in a carton	RH049 (a)	2014-Apr-08	
RH	Ethinylestradiol + Desogestrel	Tablets 0.030mg + 0.150mg	NV Organon	Kloosterstraat, Oss, The Netherlands	PVC/Alu blister further packed in an Aluminium bag 21 + 7 (placebo)	RH025 (a)	2010-Sep-29	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Bayer Pharma AG	Bayer Weimar GmbH and Co. KG, Germany (bulk manufacturing); Bayer Pharma AG, Berlin, Germany (packaging and release)	Al/PVC/PVDC blister 28 (21 active and 7 ferrous fumarate 75mg tablets per blister). 1, 3 or 6 such blisters are packed in a carton	RH003 (a)	2009-May-26	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Famy Care Ltd	Valsad, Gujarat, India	PVC/PVdC/Alu blister 1x21, 3x21, 6x21, 13x21, 100x21	RH013	2011-Sep-29	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Cipla Ltd	Goa, India	Al/PVC/PVDC/PE strip 21 + 7 (placebo) per strip, (1 or 3 strips in a carton)	RH030	2011-Dec-22	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Famy Care Ltd	Valsad, Gujarat, India	Al/PVC/PVDC blister 28 (21 active and 7 ferrous fumarate 75mg tablets per blister). 1, 3 or 6 such blisters are packed in a carton	RH038	2014-Mar-11	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Lupin Ltd	Pithampur, Madhya Pradesh, India	PVC/Aclar blister strip 3 x 28 (21 active and 7 placebo tablets per strip)	RH041 (a)	2013-Aug-26	
RH	Ethinylestradiol + Levonorgestrel	Tablets (91-day cycle pack) 30?g + 150?g	Lupin Ltd	Pithampur, Madhya Pradesh, India	PVC/Aclar blister strip 3 x 91 (84 active and 7 placebo tablets per strip)	RH042 (a)	2013-Aug-26	
RH	Ethinylestradiol + Levonorgestrel	Tablets 30?g + 150?g	Famy Care Ltd	Valsad, Gujarat, India	AL/PVC/PVDC blister 28 (21 active and 7 placebo tablets per blister). 1, 3, 6 or 100 such blisters are packed in a carton	RH035	2013-Oct-21	
RH	Etonogestrel	Implants 68mg	NV Organon	Kloosterstraat, Oss, The Netherlands	Blister pack (polyethyleneterephthalate glycol sealed with coated paper) 1 implant (in the cannula of a disposable sterile applicator)	RH020 (a)	2010-Jun-02	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
RH	Etonogestrel	Implant (X-ray detectable) 68mg	NV Organon	Kloosterstraat, Oss, The Netherlands	Blister pack (PETG sealed with HDPE lidding); 1 implant (preloaded in the stainless steel needle of a ready-to-use, disposable, sterile applicator)	RH036 (a)	2013-May-23	
RH	Levonorgestrel	Coated tablets 30?g	Bayer Pharma AG	Bayer Weimar GmbH and Co. KG, Germany	PVC/Alu blister 3 x 35	RH002 (a)	2009-May-26	
RH	Levonorgestrel	Implants (without inserter) 2 rods each with 75mg	Bayer Oy	Turku, Finland	PE bag (manufactured from spunbonded PE film and a PET/PE film), 2 rods in one package	RH017 (a)	2009-Sep-23	
RH	Levonorgestrel	Tablets 0.75mg	Gedeon Richter Plc	Budapest, Hungary	Al/PVC blister 1 x 2	RH024 (a)	2010-Aug-20	
RH	Levonorgestrel	Tablets 1.5mg	Famy Care Ltd	Ahmedabad, Gujarat, India	Al/PVC/PVDC blister 1 x 1	RH031	2013-Oct-21	
RH	Levonorgestrel	Tablets 750?g	Famy Care Ltd	Ahmedabad, Gujarat, India	PVC/PVdC/Alu blister 1x2	RH032	2013-Jun-14	
RH	Levonorgestrel	Tablets 0.75mg	Cipla Ltd	Verna, Goa, India	Al/PVC/PE/PVDC blister 1 x 2	RH040	2014-Apr-08	
RH	Lynestrenol	Tablets 500?g	NV Organon	Kloosterstraat, Oss, The Netherlands	PVC/Alu strip 1 x 28, 3 x 28	RH021 (a)	2010-Jun-02	
RH	Medroxyprogesterone acetate	Suspension for injection 150mg/ml	Pfizer	Rijksweg, Puurs, Belgium	Glass vial 1ml	RH018 (a)	2010-Aug-20	
RH	Mifepristone	Tablets 200mg	Linepharma International Ltd, United Kingdom	Laboratorios Leon Farma SA, Villaquilambre, Léon, Spain; Delpharm Lille S.A.S, Lys-Lez-Lannoy, France	PVC/PVDC/Alu blister 1x1, 30x1	RH051 (a)	2014-Oct-06	
RH	Misoprostol	Tablets 200?g	Cipla Ltd	Verna, Goa, India	Alu/Alu blister 1 x 4, 7 x 4, 15 x 4	RH039	2014-Apr-08	
RH	Norethisterone	Tablets 350?g	Lupin Ltd	Pithampur, Madhya Pradesh, India	PVC/Aclar blister strip 3 x 28	RH043 (a)	2013-Aug-26	
RH	Norethisterone	Tablets 350?g	Lupin Ltd	Pithampur, Mdhya Pradesh, India	Alu/PVC/Aclar blister (available in wallet) 3 x 28	RH045 (a)	2013-Oct-21	
RH	Norethisterone enantate	Injection 200mg/ml	Bayer Schering Pharma AG	Berlin, Germany	Glass ampoule 1ml (100 per carton)	RH022 (a)	2011-Oct-05	