

WHO List of Prequalified Medicinal Products

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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-blisters)

[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	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	2010-Sep-29	
RH	Ethinylestradiol + Levonorgestrel	Coated tablets 30?g + 150?g	Bayer Pharma AG	Bayer Weimar GmbH and Co. KG, Germany	PVC/Alu blister 3 x (21 + 7) (verum tablets + placebos)	RH003	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	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	2010-Jun-02	
RH	Levonorgestrel	Coated tablets 30?g	Bayer Pharma AG	Bayer Weimar GmbH and Co. KG, Germany	PVC/Alu blister 3 x 35	RH002	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	2009-Sep-23	
RH	Levonorgestrel	Tablets 0.75mg	Gedeon Richter Plc	Budapest, Hungary	Al/PVC blister 1 x 2	RH024	2010-Aug-20	
RH	Lynestrenol	Tablets 500?g	NV Organon	Kloosterstraat, Oss, The Netherlands	PVC/Alu strip 1 x 28, 3 x 28	RH021	2010-Jun-02	
RH	Medroxyprogesterone acetate	Suspension for injection 150mg/ml	Pfizer	Rijksweg, Puurs, Belgium	Glass vial 1ml	RH018	2010-Aug-20	
RH	Norethisterone enantate	Injection 200mg/ml	Bayer Schering Pharma AG	Berlin, Germany	Glass ampoule 1ml (100 per carton)	RH022	2011-Oct-05	