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-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
MA	Amodiaquine	Film-coated tablets 150mg	Guilin Pharmaceutical Co. Ltd	Guilin, Guangxi, China	PVC/Alu blisters 6; Cardboard box 2 x 6	MA045	2007-Aug-30	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets (co-blistered) 153mg + 50mg	Strides Arcolab Limited	Bangalore, India	Alu/PVC/PE/PVDC blister 10 x (12+12), 10 x (6+6), 10 x (3+3)	MA074	2011-Dec-22	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 67.5mg+25mg	Ipca Laboratories Ltd	Dadra and Nagar Haveli (U.T.), India	Alu/Alu blister 10x1x3, 25x3	MA080	2012-Jun-01	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 135mg+50mg	Ipca Laboratories Ltd	Dadra and Nagar Haveli (U.T.), India	Alu/Alu blister 10x1x3, 25x3	MA081	2012-Jun-01	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 270mg+100mg	Ipca Laboratories Ltd	Dadra and Nagar Haveli (U.T.), India	Alu/Alu blister 10x1x3, 10x1x6, 25x3, 25x6	MA082	2012-Jun-01	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 67.5mg + 25mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	Alu/PA/Alu/PVC blister 1 x 3	MA083	2012-Nov-16	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 135mg + 50mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	Alu/PA/Alu/PVC blister 1 x 3	MA084	2012-Nov-16	
MA	Amodiaquine (as hydrochloride) + Artesunate	Tablets 270mg + 100mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	Alu/PA/ALu/PVC blister 1 x 3, 1 x 6	MA085	2012-Nov-16	
MA	Amodiaquine + Artesunate	Tablets 153mg (200mg as hydrochloride) + Tablets 50mg	Ipca Laboratories Limited	Dadra and Nagar Haveli (U.T.), India	PVdC/PVC/Alu blister 12+12, 6+6, 3+3	MA001	2008-Apr-23	
MA	Amodiaquine + Artesunate	Tablets 150mg + 50mg	Guilin Pharmaceutical Co. Ltd	Guilin, Guangxi, China	PVC/Alu blister 3x(4+4), 3+3, 6+6, 12+12	MA046	2007-Aug-30	
MA	Amodiaquine + Artesunate	Tablets 153mg (200mg as hydrochloride) + Tablets 50mg	Cipla Ltd	Patalganga, India; Goa, India	PVC/PVDC/Alu blister 3 + 3, 6 + 6, 12 + 12	MA047	2008-Nov-11	
MA	Amodiaquine + Artesunate	Tablets 67.5mg + 25mg	Sanofi-Aventis Group	MAPHAR Laboratories, Casablanca, Morocco	Alu/Alu blister 3 x 1, 3 x 25	MA056	2008-Oct-14	
MA	Amodiaquine + Artesunate	Tablets 135mg + 50mg	Sanofi-Aventis Group	MAPHAR Laboratories, Casablanca, Morocco	Alu/Alu blister 3 x 1, 3 x 25	MA057	2008-Oct-14	
MA	Amodiaquine + Artesunate	Tablets 270mg + 100mg	Sanofi-Aventis Group	MAPHAR Laboratories, Casablanca, Morocco; Rottendorf Pharma, Ennigerloh, Germany; Batch released by: Sanofi-Aventis Maroc, Casablanca, Morocco	Alu/Alu blister 3 x 1, 3 x 25, 6 x 1, 6 x 25	MA058	2008-Oct-14	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Novartis Pharma	Beijing, China; Suffern, USA	Blister 6, 12, 18, 24	MA026	2004-Apr-26	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Ajanta Pharma Ltd	Paithan, Aurangabad, Maharashtra, India	PVC/PVdC/Alu blister 2 x 8; 3 x 8; 30 x 6; 30 x 12; 30 x 18; 30 x 24	MA052	2008-Dec-16	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Ipca Laboratories Ltd	Dadra and Nagar Haveli (U.T.), India	PVDC/PVC/Alu blister 30 x 6, 30 x 12, 30 x 18, 30 x 24	MA062	2009-Dec-15	
MA	Artemether + Lumefantrine	Tablets 20mg + 120mg	Cipla Ltd	Patalganga, Himachal Pradesh, Goa, Kurkumbh, Indore, India; Quality Chemical Industries Ltd, Kampala, Uganda	PVC-PCTFE/Alu Blister 6,12,18,24; Alu/Alu Blister 6 (1x6), 12 (2x6), 18 (3x6), 24 (4x6)	MA064	2009-May-22	
MA	Artemether + Lumefantrine	Dispersible tablets 20mg + 120mg	Novartis Pharma AG	Novartis Pharmaceuticals Corporation, Suffern, USA	PVC/PCTFE/PVC/Alu blister or PVC/PCTFE/Alu blister 30 X 6; 30 X 12; 30 X 18	MA069	2009-Feb-27	

Therapeutic area	INN	Formulation and strength	Applicant	Manufacturing site	Packaging	Reference	Date of PQ	Status
MA	Artemether + Lumefantrine	Dispersible tablets 20mg + 120mg	Ajanta Pharma Ltd	Paithan, Aurangabad, Maharashtra, India	PVC/PVdC/Alu blister 1 x 6, 30 x 6, 1 x 12, 30 x 12	MA092	2012-Dec-19	
MA	Artemotil	Solution injection 50mg/ml	Artecef BV	Rotexmedica GmbH, Trittau, Germany	Glass ampoules 1ml	MA027	2006-Mar-01	
MA	Artemotil	Solution injection 150mg/ml	Artecef BV	Rotexmedica GmbH, Trittau, Germany	Glass ampoules 1ml	MA028	2006-Mar-01	
MA	Artesunate	Tablets 50mg	Ipca Laboratories Ltd	Dadra and Nagar Haveli (U.T.), India	PVdC/Al blisters 12	MA038	2007-Aug-30	
MA	Artesunate	Tablets 50mg	Guilin Pharmaceutical Co. Ltd	Guilin, Guangxi, China	Blister 12	MA044	2005-Dec-21	
MA	Artesunate	Powder for Injection 60mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, P.R. China	Vial [1 vial of artesunate powder is co-packed with 1 ampoule of sodium bicarbonate injection (1ml:50mg) and 1 ampoule of sodium chloride injection (5ml:45mg)]	MA051	2010-Nov-05	
MA	Artesunate	Powder for injection 30mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	Vial; 1 vial of artesunate powder is co-packed with 1 ampoule of sodium bicarbonate injection (0.5mL:25mg) and 1 ampoule of sodium chloride injection (2.5mL:22.5mg)	MA089	2013-May-23	
MA	Artesunate	Powder for injection 120mg	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	Vial; 1 vial of artesunate powder is co-packed with 1 ampoule of sodium bicarbonate injection (2mL:100mg) and 1 ampoule of sodium chloride injection (10mL:90mg)	MA090	2013-May-23	
MA	Artesunate + [Sulfadoxine + Pyrimethamine]	Tablets + Tablets 50mg + [500mg + 25mg]	Guilin Pharmaceutical Co., Ltd.	Guilin, Guangxi, China	PVC/Alu blister 3 + 1; 6 + 2	MA066	2012-May-24	
MA	Artesunate + Mefloquine (as hydrochloride)	Tablets 25mg + 50mg	DNDi, Switzerland (Cipla Ltd is the supplier and is responsible for the product)	Cipla Ltd, Patalganga, India	Alu/Alu strip 1 x 3, 2 x 3	MA078	2012-Sep-12	
MA	Artesunate + Mefloquine (as hydrochloride)	Tablets 100mg + 200mg	DNDi, Switzerland (Cipla Ltd is the supplier and is responsible for the product)	Cipla Ltd, Patalganga, India	Alu/Alu strip 1 x 3, 2 x 3	MA079	2012-Sep-12	