WHO-PQ RECOMMENDED SUMMARY OF PRODUCT CHARACTERISTICS

This summary of product characteristics focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.[*]

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

[*]https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

1. NAME OF THE MEDICINAL PRODUCT

[MA147 trade name]†

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a co-packaged medicinal product, consisting of three (3) amodiaquine (as hydrochloride) tablets and one (1) pyrimethamine/ sulfadoxine tablet.

Each amodiaquine (as hydrochloride) dispersible tablet contains 150 mg amodiaquine (as hydrochloride) and each pyrimethamine/ sulfadoxine dispersible tablet contains 25 mg pyrimethamine and 500 mg sulfadoxine.

Excipients with potential clinical effect

Each pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablet contains 51 mg of isomalt. See section 4-4.

For the full lists of excipients, see section 6-1.

3. PHARMACEUTICAL FORM

Dispersible tablets.

Amodiaquine (as hydrochloride) 150 mg dispersible tablet

Pale yellow to yellow, mottled circular, biconvex (rounded on top and bottom), uncoated tablet with break line on one side and plain on the other side.

The tablet can be divided into equal halves.

Pyrimethamine/Sulfadoxine 25 mg/500 mg dispersible tablet

White to off-white, circular, flat bevelled-edged, uncoated tablet with “525” debossed (stamped) on one side and break line on the other side.

The tablet can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[MA147 trade name] is indicated for malaria prevention during the malaria season (seasonal malaria chemoprevention, SMC) in children.

Prophylaxis regimens should take into account the most recent official prophylaxis guidelines (e.g. those of the WHO) and local information on the prevalence of resistance to antimalarial drugs.

4.2 Posology and method of administration

Posology

Treatment should start at the beginning of the high transmission period and is taken in 3-day courses as follows:

† Trade names are not prequalified by WHO. This is the national medicines regulatory agency’s responsibility.

	Dose (child from 12 months to 59 months)	
	Amodiaquine tablet (150 mg)	**Sulfadoxine/Pyrimethamine tablet (500 mg/25 mg)**
Day 1	1 tablet as a single dose	1 tablet as a single dose
Day 2	1 tablet as a single dose	–
Day 3	1 tablet as a single dose	–

Children less than 12 months of age

Another formulation should be used to supply the correct dose.

Children 60 months of age or older

The recommended dose is based on bodyweight.

For *sulfadoxine/pyrimethamine* the recommended dose is 25/1.25 mg/kg bodyweight (range 25-70/1.25-3.5 mg/kg) as single dose on Day 1.

For *amodiaquine* the the recommended dose is 10 mg/kg bodyweight (range 7.5-15 mg/kg) daily on Days 1, 2 and 3.

Duration of treatment

The 3-day course is repeated at 28-day intervals, beginning at the start of the transmission season and continuing for 3–5 cycles, depending on the local context. It is important that the child receives the full 3-day course. Missing a course reduces protection but does not prevent the child receiving the next course.

Method of administration

The tablets should be dispersed in water.

Doses on day 1 should be given under the supervision of the health care provider, whereas doses on days 2 and 3 (amodiaquine only) can be taken by the child at home.

For administration of [MA147 trade name] **on the first day of treatment**, prepare a clean cup or glass,, and the required number of amodiaquine dispersible tablets and sulfadoxine/pyrimethamine dispersible tablets:

- Add approximately 10 mL of drinking water into the cup/glass;
- Place the amodiaquine and the sulfadoxine/pyrimethamine dispersible tablets into the cup/glass;
- Gently swirl the cup/glass until the tablets disperse and the contents are fully mixed, after which it should be taken immediately by the child;
- Rinse the cup/glass should with about another 10 mL of drinking water; the child should drink the contents to be sure that the whole dose is taken.

For administration of [MA147 trade name] **on the second and third day of treatment**, prepare a clean cup or glass and the required number of amodiaquine tablets

- Add approximately 10 mL of drinking water into the cup/glass;
- Place the amodiaquine dispersible tablet into the cup/glass;
- Gently swirl the cup/glass until the tablets disperse and the contents are fully mixed, after which it should be taken immediately by the child;
- Rinse the cup/glass with about another 10 mL of drinking water; the child should drink the contents to be sure that the whole dose is taken.

If a child vomits the dose within 30 minutes, they should rest for 10 minutes and a replacement dose be taken.

4.3 Contraindications

[MA147 trade name] is contraindicated in a child:

- who is hypersensitive to any of the active substances, to sulfonamide drugs or to any of the excipients of [MA147 trade name] (see section 6.1);
- with an acute febrile illness or a severe illness;
- taking co-trimoxazole (e.g. HIV-positive child receiving co-trimoxazole prophylaxis);
- who has received a dose of either amodiaquine or pyrimethamine/sulfadoxine during the previous 4 weeks;
- with a history of blood disorders with amodiaquine or pyrimethamine/sulfadoxine;
- with documented megaloblastic anaemia due to folate deficiency;
- with liver disease;
- with retinopathy.

4.4 Special warnings and precautions for use

Acute illness

[MA147 trade name] should not be given if the patient has an acute illness. If the patient has malaria, specific treatment should be given according to the most recent official guidelines.

Renal or hepatic impairment

Caution should be exercised in patients with renal or hepatic impairment.

Hypersensitivity reactions

Because of a rare risk of severe hypersensitivity reactions (see section 4.3), treatment with [MA147 trade name] should be stopped if a patient develops a rash or urticarial reaction.

Excipients

[MA147 trade name] contains **isomalt**. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

It is important to consider the contribution of excipients from all the medicines that the patient is taking.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of [MA147 trade name] with trimethoprim, or sulfamethoxazole/trimethoprim, or another sulfonamide can increase haematological side effects and the risk of severe cutaneous reactions. Concomitant use should therefore be avoided.

Seasonal malaria chemoprevention is not recommended for individuals receiving other forms of malaria chemoprevention (e.g. mass drug administration [MDA] or perennial malaria chemoprevention [PMC]).

The risk of hepatic and haematological adverse effects may increase if [MA147 trade name] is given with other medicines with hepatic or haematological toxicity.

Concomitant administration of [MA147 trade name] is not recommended with:

- medicines that inhibit the liver enzymes cytochrome (CYP) 2A6 (e.g., some beta-blockers, antidepressants, and antipsychotic drugs);
- medicines that inhibit CYP2C8 (e.g. trimethoprim, ketoconazole, ritonavir, saquinavir, lopinavir, gemfibrozil, montelukast).

4.6 Fertility, pregnancy and breastfeeding

Seasonal malaria chemoprevention with [MA147 trade name] is indicated for children and effects on pregnancy and breastfeeding are not relevant.

Pregnancy

The safety of amodiaquine in pregnant women has not been established in formal studies but many years of experience with amodiaquine do not indicate reproductive toxicity.

Pyrimethamine/sulfadoxine showed reproductive toxicity in animal studies (see 5.3).

Amodiaquine + pyrimethamine/sulfadoxine should not be used during the first trimester of pregnancy unless the benefit is considered to outweigh the risks and alternative medicines are not available.

During second or third trimesters of pregnancy, [MA147 trade name] may be used for intermittent preventive treatment in pregnancy.

Breastfeeding

Amodiaquine does not appear to be excreted in appreciable amounts in the breast milk. Pyrimethamine is excreted in human milk. Some sulfonamides are excreted in human milk.

Sulfonamides should be avoided in premature infants and in infants with hyperbilirubinaemia or glucose-6-phosphate dehydrogenase deficiency. Except for the preceding conditions, [MA147 trade name] can be used during breastfeeding.

Fertility

No human data on the effect of [MA147 trade name] on fertility are available. Animal data showed that pyrimethamine impaired fertility. Amodiaquine showed effects on spermatogenesis (see section 5.3).

4.7 Effects on ability to drive and use machines

Patients receiving [MA147 trade name] should be warned that somnolence, dizziness or asthenia may occur, in which case they should not drive or use machines.

4.8 Undesirable effects

Of the mild adverse events associated with amodiaquine, the most common are vomiting, abdominal pain, fever, diarrhoea, itching, headaches and rash. Aplastic anaemia and fatal hepatotoxicity are rarely associated with weekly prophylactic use of amodiaquine; such events have not been reported with use of amodiaquine for seasonal malaria chemoprophylaxis (see also section 5.1).

Mild adverse events associated with pyrimethamine/sulfadoxine involve the skin and mucous membranes. Serious cutaneous toxicity (Stevens–Johnson syndrome) and hepatotoxicity may occur rarely.

The adverse events listed below are not based on adequately sized studies, but on literature data generally published after approval and for the use of each of these antimalarials in adults. Frequency estimates are highly variable across the studies and no frequencies are given for many events. Side effects most relevant to seasonal malaria prevention in children are shown in **bold**.

Adverse events reported with [MA147 trade name], are listed below by body system, organ class. Where they can be estimated, frequencies are defined as *very common* (≥ 1/10), *common* (1/100–1/10), *uncommon* (1/1000–1/100), *rare* (1/10 000–1/1000) or *very rare* (≤ 1/10 000).

Amodiaquine

Nervous system disorders

Very common: weakness, **headache**, dizziness

Rare: neuromyopathy

Gastrointestinal disorders

Very common: anorexia, nausea, **vomiting**, **abdominal pain**, **diarrhoea**

Skin and subcutaneous disorders

slate-grey pigmentation, notably of the fingers and mucous membranes (usually associated with malaria treatment rather than seasonal chemoprophylaxis)

Common: **pruritus**

General disorders and administration site conditions

Common: **fever**

Eye disorders

transient accommodation disorders, corneal opacity (usually associated with malaria treatment rather than seasonal chemoprophylaxis) which reverses on stopping treatment

Very rare: irreversible retinopathy requiring care from eye specialist

Blood and lymphatic disorders

leucopoenia and neutropenia (agranulocytosis)

Hepato-biliary disorders

severe and sometimes fatal hepatitis; development of hepatic disorders may be delayed

Pyrimethamine/sulfadoxine

Gastrointestinal reactions

glossitis, stomatitis, nausea, emesis, **abdominal pain**, **diarrhoea**, feeling of fullness

Skin and subcutaneous tissue disorders

photosensensitivity, **urticaria**, **pruritus**, exfoliative dermatitis, slight hair loss, Lyell's syndrome, erythema multiforme, Stevens-Johnson syndrome, **generalised skin eruptions**, toxic epidermal necrolysis

General disorders

fever, chills, periarteritis nodosa and lupus erythematosus phenomenon

Nervous system disorders

headache, peripheral neuritis, convulsions, ataxia, hallucinations, insomnia, fatigue, muscle weakness, polyneuritis

Psychiatric disorders

depression, **nervousness**, apathy

Blood and lymphatic disorders

agranulocytosis, aplastic anaemia, megaloblastic anaemia, thrombocytopenia, leucopoenia, haemolytic anaemia, purpura, hypoprothrombinaemia, methemoglobinaemia, and eosinophilia

Cardiac disorders

allergic myocarditis/pericarditis

Ear and labyrinth disorders

tinnitus, vertigo

Endocrine disorders

Sulfadoxine, a sulphonamide is similar to some diuretics (acetazolamide and the thiazides), and sulfonylurea hypoglycaemics. Diuresis and hypoglycaemia have occurred rarely in patients receiving sulphonamide.

Eye disorders

periorbital oedema, conjunctival and scleral icterus

Hepatobiliary disorders

hepatitis, hepatocellular necrosis, pancreatitis, transient rise of liver enzymes

Immune system disorders

hypersensitivity reactions, serum sickness, anaphylactoid reactions

Musculoskeletal and connective tissue disorders

arthralgia

Renal and urinary disorders

renal failure, interstitial nephritis, blood-urea nitrogen and serum creatinine elevation, toxic nephrosis with oliguria and anuria, crystalluria

Respiratory disorders

pulmonary infiltrates resembling eosinophilic or allergic alveolitis

Reporting of suspected adverse reactions

Health care providers are asked to report adverse reactions that may be linked to a medicine, to the marketing authorisation holder, or, if available, to the national reporting system. Reports of suspected adverse reactions to a medicine are important for the monitoring of the medicine's benefits and risks.

4.9 Overdose

Amodiaquine

Symptoms: headache, dizziness, visual disorders, cardiovascular collapse, and convulsions, followed by early respiratory and cardiac arrest.

Treatment: the patient should be urgently transferred to a specialised unit for close monitoring and supportive therapy.

Pyrimethamine/sulfadoxine

Symptoms: headache, anorexia, nausea, vomiting, agitation, convulsions, haematologic changes (megaloblastic anaemia, leucopoenia, thrombocytopenia), glossitis and crystalluria.

Treatment: the patient should be urgently transferred to a specialised unit for close monitoring and supportive therapy including, where appropriate, activated charcoal and fluid administration; a parenteral benzodiazepine, phenytoin or a barbiturate can be given for convulsions. Liver and renal function should be

monitored, and blood counts checked repeatedly for up to four weeks after the overdose. Should blood dyscrasia occur, folinic acid (leucovorin) may be used.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antimalarial

Amodiaquine ATC code: P01BA06

Pyrimethamine combinations. ATC code: P01BD51

Amodiaquine is a synthetic 4-aminoquinoline antimalarial. It has schizonticidal action on *Plasmodium falciparum*, *P. vivax*, and *P. ovale* by destroying intraerythrocytic forms.

The mechanism of action of 4-aminoquinoline derivatives like amodiaquine against plasmodium is not completely known. It is nonetheless accepted that these derivatives penetrate the infected red blood cells and prevent the parasite from polymerising haeme into an insoluble product called haemozoin, leading to parasite death.

Pyrimethamine is a diaminopyrimidine. It exerts its antimalarial activity by inhibiting plasmodial dihydrofolate reductase thus indirectly blocking the synthesis of nucleic acids in the malaria parasite. It is a slow-acting blood schizontocide and is also possibly active against pre-erythrocytic forms of the malaria parasite and inhibits sporozoite development in the mosquito vector. It has in vitro activity against the four long-established human malaria parasites. There has been rapid emergence of clinical resistance.

Sulfadoxine is a sulfonamide. Sulfonamides are competitive antagonists of p-aminobenzoic acid. They are competitive inhibitors of dihydropteroate synthase, the enzyme in *P. falciparum*, which is responsible for the incorporation of p-aminobenzoic acid in the synthesis of folic acid. Therefore, by acting at a different step in folate synthesis, sulfadoxine increases the effect of pyrimethamine.

Strains of *P. falciparum* resistant to 4-aminoquinolines (chloroquine, amodiaquine) are present in many areas, and their geographical distribution is constantly changing. However, amodiaquine remains active against some chloroquine-resistant *P. falciparum* strains. *P. falciparum* can also become resistant to the effects of pyrimethamine/sulfadoxine.

Clinical efficacy

Three randomised placebo-controlled studies have looked at the efficacy of seasonal malaria prevention with amodiaquine + pyrimethamine/sulfadoxine added to other measures such as insecticidal bed-nets or home malaria management. Over 7300 children aged 3–59 months participated in the studies, all in west Africa. The protective efficacy, measured as the incidence of malaria, ranged from 66 to 82%.

A previous study had compared regimens containing pyrimethamine/sulfadoxine with either artesunate or amodiaquine in 2102 children. The incidence of malaria was lowest (5%) among children who received amodiaquine + pyrimethamine/sulfadoxine compared to those receiving artesunate-based regimens (9–11%).

5.2 Pharmacokinetic properties

The absorption characteristics of [MA147 trade name] have been determined as follows, after administration of one tablet of amodiaquine (as hydrochloride) 150 mg dispersible tablet and one tablet of pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablet in healthy volunteers in the fasted state:

Pharmacokinetic variable	Arithmetic mean ± standard deviation		
	Amodiaquine	**Pyrimethamine**	**Sulfadoxine**
Maximum concentration (C_{max})	3.91 ± 1.73 ng/mL	154 ± 21 ng/mL	65.8 ± 6.0 µg/mL
Area under the curve (AUC_{0-t}), a measure of the extent of absorption	40.1 ± 10.5 ng.h/mL	7714 ± 824 ng.h/mL	3760 ± 300 µg.h/mL
Time to attain maximum concentration (t_{max})	1.33 ± 0.91 h	4.55 ± 2.40 h	4.64 ± 6.53 h

Pharmacokinetics of pyrimethamine, sulfadoxine and amodiaquine

	Pyrimethamine	**Sulfadoxine**	**Amodiaquine**
Absorption			
Oral bioavailability	NA*	NA*	NA*
Absolute bioavailability	NA*	NA*	Amodiaquine is metabolized to its main active form, desethylamodiaquine.
Food effect	-	-	The C_{max} and $AUC_{(0-t)}$ of the active metabolite desethylamodiaquine increased 18% and 12% respectively with a high-fat meal, compared to fasting.
Distribution			
Volume of distribution (mean)	2.3 L/kg	0.14 L/kg	20 to 40 L/kg
Plasma protein binding *in vitro*	90%	90%	>90% (amodiaquine as well as desethylamodiaquine)
Tissue distribution	Widely distributed. Crosses the placental barrier and excreted in breast milk	Widely distributed. Crosses the placental barrier and excreted in breast milk	Distributed into red blood cells; blood/plasma ratio is 4-6.
Metabolism			
	Transformed to several unidentified metabolites.	5% acetylated 2-3% glucuronated	Metabolism of amodiaquine into the active metabolite, desethylamodiaquine, by CYP2C8
Active metabolite(s)	-	-	Desethylamodiaquine; further metabolized by oxidation and glucuronidation

Elimination			
Elimination half life	100 hours	200 hours	Amodiaquine: 12h Desethylamodiaquine: 9–18 days.
Mean systemic clearance (Cl/F)	NA*	NA*	Amodiaquine: 1.1 L/h*
% of dose excreted in urine	NA*	Approximately 60% is present as the acetyl derivative and 10% as the glucuronide	2% excreted unchanged
% of dose excreted in faeces	-	-	-
Pharmacokinetic linearity	NA*	NA*	Linear PK over the 200 – 600 mg dose range
Drug interactions *(in vitro*)			
Transporters		-	-
Metabolizing enzymes	-		May inhibit CYP2D6

Special populations

Renal impairment

In patients with renal insufficiency, delayed elimination of sulfadoxine and pyrimethamine is expected.

Pregnant women

During pregnancy, sulfadoxine clearance is increased. Pyrimethamine is not significantly affected.

5.3 Preclinical safety data

Amodiaquine

General toxicity

Non-clinical data reveal no special hazard for humans not already covered in other sections of the SmPC, based on conventional studies of safety pharmacology and repeated dose toxicity.

Genotoxicity

In vitro (Ames test) and in vivo tests (sister chromatid exchange and chromosome aberration tests) showed that amodiaquine, like chloroquine, has both a mutagenic and a clastogenic potential.

Carcinogenicity

No studies on the carcinogenic potential of amodiaquine have been conducted.

Reproductive toxicity

Treatment of rats with amodiaquine caused disruption of the blood-testis barrier and germ cell apoptosis without affecting body weight. The adverse effects on spermatogenesis were reversible when treatment was discontinued.

Pyrimethamine/sulfadoxine

Genotoxicity

Pyrimethamine was not found mutagenic in the Ames test. Pyrimethamine was found to be mutagenic in laboratory animals and also in human bone marrow following 3 or 4 consecutive daily doses totalling 200–300 mg.

Carcinogenesis

Pyrimethamine was not found carcinogenic in female mice or in male and female rats.

Reproductive toxicity

Sperm motility and count were significantly decreased in pyrimethamine-treated male mice, and their fertility rate fell to zero. These adverse effects were reversible when pyrimethamine was discontinued. Testicular changes have been observed in rats treated with pyrimethamine/sulfadoxine. The pregnancy rate of female rats was not affected following treatment with 10.5 mg/kg daily, but was significantly reduced at doses of 31.5 mg/kg daily or higher. Pyrimethamine/sulfadoxine was teratogenic in rats when given in weekly doses about 12 times the normal human dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Amodiaquine (as hydrochloride) 150 mg dispersible tablets
Magnesium hydroxide
Silica colloidal anhydrous
Mannitol
Crospovidone
Polysorbate
Sodium bicarbonate
Sucralose
Purified talc
Citric acid monohydrate
Orange flavour
Sodium stearyl fumarate

Pyrimethamine/Sulfadoxine 25 mg/500 mg dispersible tablets
Crospovidone
Isomalt
Methacrylic acid-methyl methacrylate copolymer
Povidone
Polyethylene glycol
Sodium bicarbonate
Citric acid monohydrate
Sucralose
Orange flavour
Silica colloidal anhydrous
Sodium stearyl fumarate

This medicine is essentially 'sodium-free'. It contains less than 1 mmol sodium (23 mg) per tablet.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30 °C. Store tablets in blisters in the provided carton in order to protect from light.

6.5 Nature and contents of container

Clear PVC/PVDC-Alu blister card containing three (3) tablets of amodiaquine (as hydrochloride) 150 mg and one (1) tablet of pyrimethamine/sulfadoxine 25 mg/500 mg.

Pack sizes: 25 or 50 blister cards per carton.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. SUPPLIER

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8. WHO REFERENCE NUMBER (WHO Prequalification Programme)

MA147

9. DATE OF PREQUALIFICATION

12 April 2021

10. DATE OF REVISION OF THE TEXT

October 2024

Section 6 was updated in June 2025

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All references accessed in July 2024

Detailed information on this medicine is available on the World Health Organization (WHO) website: https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products