1. Name of medicinal product

Maldox suspension

2. Qualitative and quantitative composition

Sulfadoxine 500mg

Pyrimethamine 25mg

For one scored tablet Excipients For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Oral suspension

4. Clinical particulars

4.1. Therapeutic indications

- Intermittent prevention of malaria in pregnant women during the 2nd and 3rd trimesters of pregnancy.
- Treatment of acute, uncomplicated P. falciparum: Maldox in combination with artesunate is recommended by WHO.

4.2. Posology and method of administration

For treatment of malaria:

- Adults and teenagers: 3 tablets as a single dose on the third day of quinine therapy.
- Children: Dose is based on body weight and must be determined by your doctor.

For self-treatment of presumed malaria:

- Adults and teenagers: 3 tablets as a single dose when you get a fever and medical care is not available.
- Children 2 months of age and older: Dose is based on body weight and must be determined by your doctor. The dose may range from ½ tablet to 3 tablets taken as a single dose.

For prevention of malaria:

- Adults and teenagers: 1 tablet once every seven days, or 2 tablets once every fourteen days.
- Children 2 months of age and older: Dose is based on body weight and must be determined by your doctor. The dose may range from ¼ tablet to ¾ tablet taken once every seven days, or ½ tablet to 1½ tablets taken once every fourteen days.

4.3 Contraindications

Maldox is contraindicated in the following cases:

• Known hypersensitivity to sulfonamides or pyrimethamine or any other ingredient

• Severe hepatic or renal insufficiencies (except when no alternative treatment is available).

• History of hepatitis due to sulfadoxine or pyrimethamine intake.

• Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.3. Special warnings and precautions for use

Maldox suspension is contraindicated in patients with severe kidney or liver failure, blood disorder, megaloblastic anemia due to folic acid deficiency, pregnancy at term and during lactation, infants ≤ 2 months old.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of Maldox suspension with trimethoprim, or sulfamethoxazole/trimethoprim, or another sulfonamide can increase hematological side effects and the risk of severe cutaneous reactions. Concomitant use should therefore be avoided.

The risk of hepatic and hematological adverse effects may increase if Maldox suspension is given with other drugswith hepatic or hematological toxicity.

4.6 Fertility, pregnancy and breastfeeding

Pregnancy

Pyrimethamine/sulfadoxine showed reproductive toxicity in animal studies. Pyrimethamine/sulfadoxine should not be used during the first trimester of pregnancy unless the benefit is considered to outweigh the risks and alternative drugs are not available.

During the second and third trimesters of pregnancy Maldox suspension may be used for intermittent preventive treatment in pregnancy.

Breastfeeding

Pyrimethamine is excreted in human milk. Some sulfonamides are excreted in human milk. Sulfonamides are avoided in premature infants and in infants with hyperbilirubinemia orglucose-6-phosphate dehydrogenase deficiency. Except for the preceding conditions, sulfonamides are compatible with breastfeeding. Maldox suspension can be used during breastfeeding.

Fertility

No human data on the effect of Maldox suspension on fertility are available.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

- Rare gastro-intestinal disorders
- Signs of skin allergic reactions: rash, itching, exceptionally severe reactions, including Stevens-Johnson and Lyell syndromes.
- Blood disorders (megaloblastic anemia, leukopenia, agranulocytosis, thrombopenia), which require treatment discontinuation and a possible IM or IV folinic acid administration.
- Hepatic function disorders: rare cases of transaminase level increase and hepatitis have been reported Skin reactions or blood disorders require an immediate and definitive discontinuation of the treatment

4.9. Overdose

Symptoms

High doses of pyrimethamine are potentially fatal. Prominent symptoms of overdose are anorexia, vomiting and seizures. Induction of emesis or gastric lavage is of value if undertaken within a few hours after ingestion.

Treatment

The patient should be urgently transferred to a specialized 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

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 schizonticide and is also possibly active against preerythrocytic forms of the malaria parasite and inhibitssporozoite 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.

P. falciparum can become resistant to the effects of pyrimethamine/sulfadoxine.

5.2 Pharmacokinetic properties
Absorption

After oral administration both sulfadoxine and pyrimethamine are well absorbed (bioavailability of >90%) in healthy adults.

Distribution

The volume of distribution for pyrimethamine and sulfadoxine is 2.3 l/kg and 0.14 l/kg, respectively. Plasma protein binding is about 90% for both pyrimethamine and sulfadoxine. Both cross the placental barrier and pass into breast milk.

Metabolism

Pyrimethamine is transformed to several unidentified metabolites. About 5% of sulfadoxine appears in the plasma as acetylated metabolite, about 2 to 3% as the glucuronide.

Elimination

The elimination half-lives are about 100 hours for pyrimethamine and about 200 hours for sulfadoxine. Both are eliminated mainly through the kidneys.

5.3 Preclinical safety data

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

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 totaling 200–300 mg.

Carcinogenesis

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

6. Pharmaceutical particulars

6.1 List of Excipients

Purified water

Sorbitol

Sodium carboxymethylcellulose

Sodium benzoate

Citric acid

Disodium Edetate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in below 30°C. Protect from Moisture.

6.5 Nature and contents of container

30g amber glass bottle fitted/sealed with aluminum cap along with dropper.

Pack size: 30ml

6.6 Special precautions for disposal and other handling

SHAKE WELL BEFORE USE.

Dilution is not recommended as this may reduce therapeutic efficacy.

Any unused medicinal product or waste material should be disposed of in accordance

with local requirements.

7. Marketing authorization holder

Emzor Pharmaceutical Industries Limited.

Kolawole Shonibare street, Ajao Estate, Isolo, Lagos state

8. Marketing authorization number(s)

04-4345

9. Date of first authorization/renewal of authorization

July 2005

10. Date of revision of text

August 20th,2025