SUMMARY OF PRODUCT CHARACTERISTICS(SPC)

1. NAME OF THE MEDICINAL PRODUCT

Malakant Dispersible 500mg/25mg Dispersible Tablets

2. QUALITATIVE AND QUANTITATIVE

Each uncoated dispersible tablet contains:
Sulfadoxine Ph.Eur .....500 mg
Pyrimethamine Ph.Eur... 25 mg

For full list of excipients see section 6.1.

3.PHARMACEUTICAL FORM

Solid oral dosage form: dispersible tablets

White to off white, flat beveled edged, uncoated dispersible tablets, debossed with "525" on one side and with breakline on other side.
Tablet having functional scoring which can be divided into equal halves.

4.CLINICAL PARTICULARS

4.1 Therapeutic Indications

IPTp (Intermittent Preventive Treatment in pregnant women)
Malakant dispersible may be used for IPTp along with other prevention and control measures of malaria in pregnant women. IPTp with Malakant dispersible is restricted to pregnant women in areas with high or moderate stable transmission level of uncomplicated P. falciparum malaria.

4.2 Posology and method of administration

Intermittent Preventive Treatment (IPTp) of Malaria

Pregnant women residing in areas with HIV prevalence less than 10% at least two doses of 1500 mg Sulfadoxine and 75 mg Pyrimethamine each=3 tablets as a signal dose at two separate occasions, one during the second trimester of pregnancy (after quickening), one during the third trimester of pregnancy, the two administrations being separated by at least one month.

Pregnant women residing in areas with HIV prevalence more than 10% at least three doses of 1500 mg Sulfadoxine and 75 mg Pyrimethamine each=3 tablets as a signal dose at three separate occasions during second & third trimester of pregnancy & each administration should be separated by at least one month interval.

Method of administration

- Place the Malakant Dispersible tablet (s) in a small amount of water (approximately 10 ml per tablet) in a cup. Allow the tablet to disintegrate and

- stir gently until a uniform suspension is obtained and drink now.
- Afterwards immediately rinse the cup with approximately 10 ml of water and drink it now. Make sure all the medicine is consumed. If vomits within 30 minutes taking the tablet, take another dose as soon as possible. After 30 minutes no replacement dose is required.

4.3 Contraindications

Hypersensitivity to any of the active substances or excipients listed under "'Composition".
Cough, shortness of breath: The product should be discontinued if symptoms such as cough or shortness of breath occur during treatment with Malakant Dispersible.
Skin reactions: The medication must be immediately withdrawn if skin reactions occur, as this could indicate a life-threatening reaction to the drug.

4.4 Special warnings Warning and precautions for use

Excessive sun exposure must be avoided at all cost. Patients should be advised that soar throat, fever , cough , shortness of breath & purpura may be first signs of serious side effects. In particular, Malakant dispersible must be withdrawn at first sign of a skin rash ,a significant decrease in blood cells , or bacterial or fungal super infections.
Patients taking Malakant dispersible must ensure adequate fluid intake in order to avoid the development crystalluria
Sugar intolerance : MALAKANT DISPERSIBLE contains Isomalt :
Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interactions with other medicinal products and other forms of interaction

Coadministration of Malakant dispersible with trimethoprim and trimethoprim-sulfonamide combinations may result in an increased antifolate effect with corresponding haematological side-effects and should therefore be avoided.
There is evidence that side-effects occur more often and are more severe during combined use of Malakant dispersible and chloroquine than with Malakant dispersible alone.

4.6 Pregnancy & Lactation

Pregnancy
In animal experiments folic acid administration in the form of leucovorin abolished embryotoxic and teratogenic effects. In pregnant women prophylactic and therapeutic use of Malakant Dispersible produced no evidence of embryofetal damage.
IPTp with Malakant Dispersible, given 2 or 3 times to pregnant women residing in areas of high or moderate stable malaria transmission reduces the risk of low birth weight in babies born to primi- and secundi-gravidae, and HIV positive multi-gravidae, thus

increasing the probability of child survival. IPTp with Malakant Dispersible reduces the incidence of malarial anemia in primi- and secundi-gravidae women. IPTp with Malakant Dispersible should be used along with other prevention and control measures of malaria.

A folate supplement should also be given.

4.7 Effects on ability to drive and use machines:

Because of the possible side-effects of the product, such as nausea, vomiting or dizziness, caution is required when driving vehicles or operating machinery.

4.8 Undesirable Effects

The following side-effects and hypersensitivity reactions can occur with products containing sulfonamides and/or pyrimethamine:

Blood

Rare: Generally asymptomatic thrombocytopenia. Megaloblastic anemia, leukopenia.

Very rare: Agranulocytosis or purpura.

As a rule of changes regress after withdrawal of the product.

Gastrointestinal disorders

Feeling of fullness, nausea.

Rare: Vomiting, diarrhoea, stomatitis.

Hepatobiliary disorders

Very rare: Transient rises in liver enzymes, as well as hepatitis and hepatocellular damage, have been observed in temporal association with Malakant Dispersible use.

Skin

Occasional: Drug rashhes, pruritus, urticaria, photosensitisation and hair loss. These reactions are usually mild and regress spontaneously on withdrawal of the drug.

Rare: Particularly in hypersensitive patients, severe, possibly life threatening skin reactions such as erythema multiforme, Stevens-Johnson syndrome and Lyell's syndrome may occur.

General disorders

Occasional: Fatigue, dizziness, headache, fever, polyneuritis.

Rare: Pulmonary infiltrates resembling eosinophilic or allergic alveolitis.

Very rare: Serum sickness and allergic pericarditis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the National Regulatory Authority via Pharmacovigilance Electronic

Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose

Possible symptoms

Headache, anorexia, nausea, vomiting, signs of excitation, possibly convulsions,hematological changes (megaloblastic anaemia, leukopenia, thrombocytopenia).

Measures

In acute intoxication gastric lavage and fluid replacement, for convulsions parenteral diazepam or a barbiturate. Monitoring of hepatic and renal function and repeated blood counts for up to four weeks after overdosage. If the above hematological changes are present, administer folinic acid (leucovorin) intramuscularly.

5.PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Malakant dispersible acts on the asexual intraerythrocytic form of the human malaria parasite *Plasmodium falciparum* . The synergistic action of the two components, sulfadoxine and pyrimethamine. inhibits two enzymes involved in the biosynthesis of folinic acid in the parasites.

Malakant dispersible is also effective against strains of *P. falciparum* resistant to chloroquine.

However, strains of *P.fa/ciparum* also clinically resistant to Malakant Dispersible are common in parts of South-East Asia and South America, and to some extent also in East and Central Africa. Malakant Dispersible should therefore be used with caution in these areas.

5.2 Pharmacokinetic properties

Absorption

After administration of 1 tablet, peak plasma levels for pyrimethamine (approximately 0.2 mg/l) and for sulfadoxine (approximately 60 mg/l) are reached after 4 hours.

Distribution

The volume of distribution is 0.14 l/kg for sulfadoxine and 2.3 l/kg for pyrimethamine. Dosing with 1 tablet weekly (recommended adult dose for malaria prophylaxis) can be expected to produce mean steady-state plasma concentrations of 0.15 mg/l for pyrimethamine (after about four weeks)
and approximately 98 mg/1 for sulfadoxine (after about seven weeks).
The sulfadoxine concentration in the erythrocyte fraction of blood is approximately 3 %

of that in plasma. Pyrimethamine reaches around 50 % of its plasma concentration in the erythrocytes.

Pyrimethamine and sulfadoxine are approximately 90 % bound to plasma proteins. Pyrimethamine and sulfadoxine cross the placental barrier and pass into breast milk.

Metabolism

About 5 % of sulfadoxine appears in the blood as acetylated metabolite, about 2-3 % as the glucuronide. Pyrimethamine is converted to various metabolites.

Elimination

A relatively long elimination half-life is characteristic of both components. The mean values are about 100 hours for pyrimethamine and about 200 hours for sulfadoxine. Both pyrimethamine and sulfadoxine are eliminated mainly via the kidneys.

Pharmacokinetics in Special Patient Groups

In malaria patients, individual pharmacokinetic parameters may differ from those in healthy subjects, depending on the population studied.

In patients with renal failure, delayed elimination of the active substances of Malakant Dispersible must be anticipated.

5.3 Preclinical safety data

With reference to available literatures.

Pyrimethamine was not mutagenic in bacterial *in vitro* tests. But showed genotoxic properties *in vivo* in laboratory animals and in human bone marrow on administration of 3 - 4 daily doses totalling 200 - 300 mg. The relevance of this observation is unclear because pyrimethamine showed no carcinogenic properties in rats or female mice: the results in male mice could not be interpreted because or markedly reduced life-span. No further relevant non-clinical data exist on sulfadoxine or the Sulfadoxine/pyrimethamine combination.

6.PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methacrylic Acid-Methyl Methacrylate Copolymer
Povidone
Polyethylene Glycol
Isomalt
Sodium bicarbonate
Citric acid Monohydrate
Sucralose, Flavour orange SD
Silica colloidal anhydrous

Crospovidone
Sodium Stearyl fumarate.

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

Proposed shelf life of 24 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. Keep the medicine out of reach of children.

6.5 Nature and contents of container

3 dispersible tablets of Sulfadoxine / Pyrimethamine in a ALU–PVC coated with PVDC blister pack in a printed carton with a printed insert.

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

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8. MARKETING AUTHORIZATION NUMBER:

H2026/CTD7869/15054

9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION

2026 May 12

10. DATE OF REVISION OF THE TEXT

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