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VERSION NO.: 007	**PACKAGING MATERIAL SPECIFICATION**	SUPERSEDES PMS/B2101700/006
FALCIDIN TABLETS INFORMATION LITERATURE INSERT		

CAUTION
Do not make any changes without authorization

INSERT SAMPLE
(Ref. No. B2123500/22.02)

23500
Ref. No: B2123500/22.02

Falcidin® (Tablets)

Sulfadoxine
Pyrimethamine
Antimalarial

FALCIDIN ® 500:25MG TABLETS

PRESENTATION:
Falcidin® Tablets 500:25mg: White, circular, flat bevelled-edge tablet embossed 'FALCIDIN∆' on one side and a two breaklines on the other side. Each tablet contains: Sulfadoxine 500mg and Pyrimethamine 25mg.

CLINICAL PHARMACOLOGY:
Synergy exists between sulfadoxine and pyrimethamine, which act against folate metabolism at different points of the metabolic cycle. Sulfonamides have a similar structure to p-aminobenzoic acid and interfere with the synthesis of nucleic acids in sensitive micro-organisms by blocking the conversion of p-aminobenzoic acid to the coenzyme dihydrofolic acid, a reduced form of folic acid. Pyrimethamine is a diaminopyrimidine antimalarial. Pyrimethamine exerts its antimalarial activity by inhibiting plasmodial dihydrofolate reductase, thus indirectly blocking the synthesis of nucleic acids in the malaria parasite. It is active against pre-erythrocytic forms and is also a slow-acting blood schizontocide. It is mainly effective against *Plasmodium falciparum* but has some activity against *P.vivax*.

Pharmacokinetics:
Sulfadoxine is readily absorbed from the gastro-intestinal tract. High concentrations in the blood are reached in about 4 hours; the half-life in the blood is about 4 to 9 days. About 90 to 95% is reported to be bound to plasma proteins. Sulfadoxine is widely distributed to body tissues and fluids; it passes into the foetal circulation and has been detected in low concentrations in breast milk. Sulfadoxine is excreted very slowly in urine, primarily unchanged. Pyrimethamine is almost completely absorbed from the gastro-intestinal tract and peak plasma of about 260 to 1411ng/ml. are obtained 2 to 4 hours after administration of 25mg orally. It is metabolised in the liver and slowly excreted via the kidney, the average half-life in plasma being about 4 days. About 80-90% is bound to plasma proteins.

USES:
Falcidin® may be used for Intermittent Preventive Treatment in pregnant women along with other prevention and control measures of malaria in pregnant women. Intermittent Preventive treatment in pregnant women with Falcidin® is restricted to areas with high or moderate stable transmission level of uncomplicated *P.falciparum* malaria.

DOSAGE AND ADMINISTRATION:
Pregnant women residing in areas with HIV prevalence less than 10%, at least two doses of 1500mg sulfadoxine and 75mg pyrimethamine each = 3 Falcidin tablets as a single dose at two separate occasions, one during the 2nd trimester of pregnancy (after quickening), one during the third trimester of pregnancy, the two administrations being separated by at least one month.
Pregnant women living in areas where HIV prevalence more than 10%, at least three doses of 1500mg sulfadoxine and 75mg pyrimethamine each = 3 Falcidin tablets as a single dose at three separate occasions, one or two during the second trimester of pregnancy (after quickening), one or two during the third trimester of pregnancy. Two consecutive administrations should be separated by at least one month interval.

Falcidin® (Tablets)

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Sulfadoxine
Pyrimethamine
Antimalarial

FALCIDIN ® 500:25MG TABLETS

02/11/23

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02/11/23

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Nairobi, Kenya

Falcidin® (Tablets)

Method and duration of use:
The tablets should be swallowed whole with plenty of fluid after a meal.

CONTRA-INDICATIONS AND WARNINGS:
Contra-indicated in patients with a known history of hypersensitivity to Sulphonamides, Sulphones or Pyrimethamine. Patients with severe renal impairment, blood dyscrasias, glucose-6 phosphate dehydrogenase (G-6-PD) deficiency, premature and new-born infants and in breast-feeding mothers. Not recommended in pregnancy but use must be weighed against the risks. Treatment must be immediately discontinued upon the appearance of any mucocutaneous signs or symptoms such as pruritis, erythema, rash, urogenital lesions or pharyngitis and a medical practitioner should be consulted. The possibility of an adverse drug reaction should be considered in patients developing a rash, jaundice, fever or severe generalized malaise during treatment with Falcidin®. Falcidin® should not be given to patients with folate deficiency conditions such as megaloblastic anaemia.
Precaution: Care should be exercised before prescribing Falcidin® for patients with impaired renal or hepatic function, to those with a history of allergies or bronchial asthma.
Adverse Effects: Fatigue, headache, fever and polyneuritis. Patients must be advised to take adequate fluids to prevent crystalluria and stone formation.
Overdosage: Possible symptoms of overdosage include anorexia, nausea, vomiting and convulsion. Treatment is symptomatic and may include forced diuresis and gastric lavage.
Interactions: Sulphonamides may potentiate the effects of some drugs, such as oral anticoagulants, methotrexate and phenytoin. Use of pyrimethamine with other folate antagonists' such as co-trimoxazole, trimethoprim, methotrexate, or phenytoin may exacerbate bone marrow depression.

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Prescription Only Medicine (POM)

®Regd. TM

COSMOS

Cosmos Limited,
Rangwe Rd; Off Lunga Lunga Rd,
Nairobi, Kenya