Dyrax®

Dihydroartemisinin 40 mg + Piperaquine Phosphate 320 mg

swipha

COMPOSITION

(3R-5aS, 6R, 8aS, 9R, 12S, 12aR) - Octahydro - 3, 6, 9 - trimethyl-3, 12-epoxy-12H-pyrano-[4, 3-j] - 1, 2 - benzodioxepin -10 (3H) - one (Dihydroartemisinin, DHA) and 1, 3 di [4-(7-Chlorine-quinoline-4-methyl) - piperazine-1-methyl] propane and tetradic phosphate (Piperaquine Phosphate, PQP) combination.

Each tablet contains:
Dihydroartemisinin .....40 mg
Piperaquine Phosphate .....320 mg

PHARMACOLOGY AND PHARMACOKINETICS

Dihydroartemisinin:

The site of antiparasitic action is the food vacuole of the malarial parasite which involves two steps. First, heme iron within the parasite catalyzes cleavage of the endoperoxide bridge. This is followed by rearrangement to produce a carbon-centered radical that alkylates and damages macromolecules in the parasite.
Absorption after oral dosing is rapid and typically 30% or less. Peak plasma levels are attained 1 hour after administration, with a half-life of about 4 hours.

It is widely distributed in the liver, kidney and bile. Approximately 80% is excreted through the urine and faeces within 24 hours after administration. It is metabolised to two inactive metabolites, deoxydihydroartemisinin and dihydroxydihydroartemisinin.

Mode of action Piperaquine Phosphate: (PQP)

Experimental results show that PQP interferes with the physiological function of the food vacuole membrane of the trophozoites leading to autophagocytosis of the parasites. It has no marked effect on the ring forms, immature or mature schizonts and the male or female gametocytes.
Upon oral administration about 80 - 90% is absorbed within 24 hours. It is widely distributed in the body mainly in the liver, kidneys, lungs and spleen. About 25% of the total dose is partitioned in the liver within 8 hours of intake. Elimination is very slow with the half life of about 94 days. It is excreted through bile by hepatoenteral circulation.

INDICATIONS

Treatment of clinical attacks of Malaria caused by *P. falciparum, P. vivax* and *P. malariae*

DOSAGE AND ADMINISTRATION

Oral Administration:

Patient should follow doctor's instruction. The recommended dosage are shown in the table below.

Weight (Kg)	11 to < 17	17 to < 25	25 to < 36	36 to < 60
Day 1	1 tablet	1½ tablets	2 tablets	3 tablets
Day 2	1 tablet	1½ tablets	2 tablets	3 tablets
Day 3	1 tablet	1½ tablets	2 tablets	3 tablets
Total	**3 tablets**	**4½ tablets**	**6 tablets**	**9 tablets**

CONTRAINDICATIONS
Dyrax® is not recommended for use for women during the first 3 months of pregnancy and in patients with liver diseases. This drug should not be taken repeatedly in four weeks after first treatment course.

SPECIAL WARNINGS AND PRECAUTIONS
Do not exceed the stated dosage.
Lactation: Excretion of Dyrax® through breast milk has not been established.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Patients **receiving** Dyrax® should be warned that dizziness might occur in which case they should be advised not to drive or use machines.

UNDESIRABLE EFFECTS
1. Nausea or vomiting may occur
2. The Dihydroartemisinin would for certain individual, bring effect of greater or lesser severity; for example, a reversible reduction in reticulocyte counts
3. Possible side-effect of PQP include mild dizziness, vertigo, headache, nausea, vomiting and abdominal discomfort. Reversible leucopenia was infrequently reported; dyspnea and palpitations were also reported but not further specified.

INTERACTIONS
None Known

STORAGE
Store in cool & dark place protect from light, store below 30°C

INSTRUCTIONS FOR USE AND HANDLING
Dyrax® should be kept out of the reach of children.

PRESENTATION
Dyrax® tablets come in a pack containing one blister of nine tablets.

NAFDAC Reg. No.: A4-9171
Mfg. Lic No.: G/1392

KEEP MEDICINE OUT OF REACH OF CHILDREN

swipha
swiss pharma nigeria Ltd.
Manufactured by:
Vapi Care Pharma Pvt. Ltd.,
Plot No 225/3. G.I.D.C.,
Near Morarji Circle, Vapi - 396 - 195, Gujarat, India.

For: swiss pharma nigeria Ltd.,
5, Dopemu Road, Agege, Lagos.

Version 1 valid as of 08/19 Rev:1