Robic®
Ornidazole

COMPOSITION
Robic® Tablet : Each tablet contains Ornidazole INN 500 mg.

PHARMACOLOGY
Robic® (Ornidazole) is rapidly absorbed from the GI tract and peak plasma concentrations of about 30 µgm per ml have been achieved within 2 hours of a single dose of 1.5 gm, falling to about 9 µgm per ml after 24 hours and 2.5 µgm per ml after 48 hours. The plasma elimination half-life is 12-14 hours. Less than 15% is bound to plasma proteins. **Robic®** (Ornidazole) is widely distributed in body tissues and fluids, including the cerebrospinal fluid. It is extensively metabolised in the liver (95%) and excreted in the urine, mainly as conjugates and metabolites, and to a lesser extent in the faeces. Billiary excretion is important in the elimination of **Robic®** (Ornidazole) and its metabolites.

INDICATION
Robic® is indicated for:
Amoebiasis (Intestinal and hepatic), Giardiasis, Trichomoniasis, Bacterial vaginosis, Treatment of susceptible anaerobic infections

DOSAGE AND ADMINISTRATION
Amoebiasis
Adults: 500 mg twice a day for 5 days.
Children: 10-25 mg per kg body weight in two divided doses.
Amoebic dysentery
Adults: 1.5 gm once a day for 3 days.
Children: 40 mg per kg body weight, once a day for 3 days.
Giardiasis
Adults: 1.5 gm once daily for 1-2 days.
Children: 40 mg per kg body weight for 2 days.
Trichomoniasis: 1.5 gm once or 500 mg twice a day for 5 days. Sexual partner should also be treated at the same time.
Bacterial vaginosis: 3 tablets of 500 mg each as a single dose or one tablet of 500 mg once daily for 5-7 days.

CONTRAINDICATION AND PRECAUTION
Previous hypersensitivity to Ornidazole and to other nitroimidazoles. Ornidazole is contraindicated in central nervous system disorders, particularly in epilepsy or in peripheral neuropathy. In patient with ataxia, vertigo, and mental confusion, Ornidazole should be prescribed with caution. During prolonged treatment with Ornidazole, blood dyscrasia namely mild leukopenia have been reported rarely. In case leukopenia occurs, the decision to discontinue the therapy should depend upon the gravity of infection.

SIDE EFFECT
Side effects of Ornidazole have been mainly limited to the gastrointestinaltract (nausea, vomiting, epigastric pain) and central nervous system (dizziness, headache, lassitude). Unlike other nitroimidazoles, Ornidazole does not interact with alcohol, although this requires further study. Leukopenia has been described occasionally during therapy. Adverse
central nervous system (CNS) effects of Ornidazole have mainly included headache, dizziness, lassitude or somnolence, fatigue and weakness. Adverse CNS effects of Ornidazole may be less than that happens with metronidazole. Seizures have not been reported with Ornidazole in studies available to date.

DRUG INTERACTION
Like other imidazoles, Ornidazole has a mild potential to cause disulfiramlike reactions. Concomitant administration of oral anticoagulants may increase the risk of haemorrhage due to diminished hepatic metabolism. Ornidazole has been reported to decrease the clearance of 5-fluorouracil.

USE IN PREGNANCY AND LACTATION
Adequate clinical trials have not been conducted. Ornidazole should be prescribed only if the potential benefit justifies the potential risk to foetus/neonate.

STORAGE CONDITION
Store at room temperature and protect from light and moisture.

HOW SUPPLIED
Robic® Tablet : Box containing 5 x 6 tablets in blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Bangladesh