TRINAZOLE-S TABLET 200MG

Each tablet contains:-
Metronidazole 200mg

Pharmacodynamics:
Metronidazole possesses direct trichomonacidal amebacidal activity against Trichomonas vaginalis and Entamoeba histolytica. The in vitro minimal inhibitory concentration for most strains of these organisms is 8ug/ml or less. Its mechanism of antiprotozoal action is unknown.
Metronidazole is active in vitro against most obligate anaerobes but does not appear to possess any clinically relevant activity against facultative anaerobes or obligate aerobes. Against susceptible organisms, metronidazole is generally bactericidal at concentrations equal to or slightly higher than the inhibitory concentrations.
Metronidazole has been shown to have in vitro and clinical activity against the following organisms:
Anaerobic gram negative bacilli, including:
Bacteroides fragilis group *(B. fragilis, B.ovatus, B.thetaiotaomicion, B.vulgatus)*
Fusobacterium species
Anaerobic gram positive bacilli, including:
Clostridium species and susceptible strains of Eubacterium.
anaerobic gram positive cocci, including:
Peptococcus species, Peptostreptococcus species

Pharmacology:
Following oral administration, Metronidazole is well absorbed with peak plasma concentrations occuring between one and two hours after administration. For oral dosage form, the elimination half-life in healthy human is eight hours. The major route of elimination of Metronidazole and its metabolites is via the urine (60-80%) of the dose), with fecal excretion accounting for 6-15% of the dose. Renal clearance of Metronidazole is approximately 10ml/min/1.73m.
Metronidazole appears in cerebrospinal fluid, saliva and breast milk in concentrations similar to those found in plasma.
Decreased renal function does not after the single-dose pharmacokinetics of Metronidazole. However, plasma clearance of metronidazole is decreased in patients with decreased liver function.

Indications:
Metronidazole is indicated for the treatment of symptomatic trichomoniasis in females and males when the presence of trichomonad has been confirmed by appropriate laboratory procedures. Metronidazole is indicated in the treatment of asymptomatic females when organism is associated with endocervicitis, cervicitis or cervical erosion. T. vaginalis infection is a venereal disease. Therefore, asymptomatic sexual partners of treated patients should be treated simultaneously if the organism has been found to be present; in order to prevent reinfection of the partner.
Metronidazole is indicated in the treatment of acute intestinal amoebiasis (amoebic dysentery) and amoebic liver abscess. Metronidazole is also indicated in the treatment of serious infections caused by susceptible anaerobic bacteria.

Adverse Effects:
The two most serious adverse reactions reported in patients treated with Metronidazole have been convulsive seizures and peripheral neuropathy, the latter characterized mainly by numbness of an extremity. Others include gastrointestinal discomfort, anorexia, nausea, coated tongue, dry mouth and unpleasant taste, headache, pruritus and skin rash and less frequently vomiting, diarrhoea, weakness, vertigo, ataxia,depression, insomnia, drowsiness discomfort and darkening of the urine.

Warning and Precautions:
Metronidazole should be administered with caution to patients with central nervous system disease. The appearance of abnormal neurologic signs demands the prompt discontinuation of Metronidazole therapy. Patients with severe hepatic disease metabolize Metronidazole slowly, with resultant accumulation of Metronidazole and its metabolites in the plasma. Accordingly, for such patients, doses below those usually recommended should be administered cautionly.
Metronidazole is a nitroimidazole are should be used with care in patients with evidence of or history of blood dyscrasia. Amild leukopenia has been observed during administration. Total and differential leukocyle counts are recommended before and after therapy for trichomoniasis and amoebiasis, especially if a second course of therapy is necessary and after therapy for anaerobic infections.
Cases of severe hepatotoxicity/acute hepatic failure, including cases with a fatal outcome with very rapid onset after treatment initiation in patients with Cockayne syndrome have been reported with products containing metronidazole for systemic use. In this population, metronidazole should therefore be used after careful benefit-risk assessment and only if no alternative treatment is available. Liver function tests must be performed just prior to the start of therapy, throughout and after end of treatment until liver function is within normal ranges, or until the baseline values are reached. If the liver function tests become markedly elevated during treatment, the drug should be discontinued.
Patients with Cockayne syndrome should be advised to immediately report any symptoms of potential liver injury to their physician and stop taking metronidazole.

Usage during Pregnancy and Lactation:
There are no adequate and well-controlled studies in pregnant women.
Use Metronidazole should be avoided during pregnancy, especially the first trimester and especially high -dose regimens.
As Metronidazole is secreted in breast milk, a decision should be made to discontinue nursing or the drug taking into account the importance of the drug to the mother.

Contraindications:
Hypersensitivity to any of its ingredients.
First trimester of pregnancy.

Dosage:
Oral administration.
Trichomoniasis :
In the female : One day treatment - 2g of Metronidazole given either as a single or in two divided doses of 1g each given in the same day.
Seven day course of treatment - 250mg three time daily for seven consecutive days.
When repeat course of the drug are required, it is recommended that an interval of 4 to 6 weeks elapse between course and that the presence of the trichomonad be reconfirmed by appropriate laboratory measures.
In the male : Treatment should be individualised as for the female.
Amoebiasis :
Adults : For acute intestinal amoebiasis (acute amoebic dysentery); 750mg orally three times daily for 5 to 10 days.
: For amoebic liver abscess : 500mg or 750mg orally three times daily for 5 to 10 days.
Children : 35 to 50mg/kg/24 hours, divided into three doses, orally for 10 days.
Anaerobic Bacterial Infections:
The usual adult oral dosage is 7.5mg/kg every six hours. A maximum of 4g should not be exceeded during a 24-hour period. The usual duration of therapy is 7 to 10 days.

Drug Interactions:
Metronidazole has been reported to potentiate the anticoagulant effect of warfarin and other oral coumarin anticoagulants, resulting in a prolongation of prothrombin time.
The simultaneous administration of drugs that induce microsomal liver enzymes, such as phenytoin or phenobarbital may accelerate the elimination of Metronidazole, resting in reduced plasma levels; impaired clearance of phenytoin has also been reported.
The simultaneous administration of drugs that decrease microsomal liver enzyme activity, such as cimetidine, may prolong the half-life and decrease plasma clearance of Metronidazole. In patients stabilized on relatively high doses of lithium, short term Metronidazole therapy has been associated with elevation of serum lithium and in a few cases, signs of lithium toxicity. Serum lithium and serum creatinine levels should be obtained several days after beginning Metronidazole to detect any increase that may precede clinical symptoms of lithium intoxication.
Alcoholic beverages should not be consumed during Metronidazole therapy and for at least three days afterward because abdominal cramps, nausea, vomiting, headached and flushing may occur.
Psychotic reaction have been reported in alcoholic patients who are using Metronidazole and disulfiram concurrently. Metronidazole should not be given to patients who have taken disulfiram within the last 2 weeks.

Symptoms and Treatment for Overdosage and Antidote(s):
Single oral doses of Metronidazole, up to 15g, have been reported in suicide attempts and accidental overdoses. Symptoms reported include nausea, vomiting and ataxia.
Neurotoxic effect, including seizures and peripheral neuropathy, have been reported after 5 to 7 days of doses of 6 to 10.4g every other day.
There is no specific antidote for metronidazole overdose, therefore, management of the patient should consist of symptomatic and supportive therapy.

Effects on Ability to Drive and Use Machines:
While taking Metronidazole you may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) or temporary eyesight problems (such as blurred or double vision). If this happens, do not drive or use any machinery or tools.

Pack Size: Blister pack: A box of 10 x 10, 50 x 10 and 100 x 10 tablets per strip.

Shelf-Life: 5 years

Storage Conditions: Store at or below 30°C.

Description: Round, off-white, convex, plain tablet with "SW" debosssed.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer:
Sunward Pharmaceutical Pte. Ltd.
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Singapore 627943

Product Registration Holder:
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