TRICOZOLE®

Metronidazole preparations

COMPOSITION:
Tricozole 200 Tablets: Each tablet contains Metronidazole BP 200 mg.
Tricozole 400 Tablets: Each tablet contains Metronidazole BP 400 mg.
Tricozole Suspension: Each 5 ml contains Metronidazole (as Benzoate BP) 125 mg.
Tricozole Suspension: Each 5 ml contains Metronidazole (as Benzoate BP) 200 mg.

INDICATIONS:
Tricozole or Metronidazole preparations are indicated in the treatment of infections caused by pathogens sensitive/ susceptible to metronidazole as underlined above and specified in the dosage regime below.

DOSAGE AND ADMINISTRATION:
Tricozole or Metronidazole preparations are administered orally for the various conditions according to the following dosage regimens.

1. **Treatment of bacterial infections**
   Adults and children over 10 years: 800mg followed by 400mg at eight hourly intervals.
   Treatment is usually for 7 days but will depend upon your condition.
2. **Treatment of anaerobic infections**
   Children 8 weeks-12 years: 20-30mg/kg/day as a single dose or divided into 7.5mg/kg every 8 hours for 7 days.
   Children under 8 weeks: 15mg/kg/day as a single dose or divided into 7.5mg/kg every 12 hours
3. **Treatment of infection caused by Trichomonas**
   Adults and adolescents: 2g as a single dose, or 200mg three times a day for 7 days, or 400mg twice a day for 5 to 7 days.
   Both partner should also be treated.
   Children under 10 years: 40mg/kg as a single dose or 15- 30mg/kg/day two to three times daily for 7 days.
4. **Treatment of non-specific genital infection in women:** 400mg twice a day for 7 days, or 2g as a single dose for 1 day only.
   Adolescent girls: 400mg twice daily for 5 to 7 days or 2g as a single dose.
5. **Treatment of amoebiasis**
   Adults and children over 10 years: 400mg-800mg three times a day for 5 to 10 days.
   Children 7-10 years: 200mg-400mg three times a day for 5 to 10 days.
   Children 3 -7 years: 100mg-200mg four times daily for 5 to 10 days.
   Children 1 -3 years: 100mg-200mg three times daily for 5 to 10 days. Or 35-50mg/kg/day in 3 divided doses for 5 to 10 days.
6. **Treatment of giardiasis**
   Adults and children over 10 years: 2g once a day for 3 days, or 400mg three times a day for 5 days or 500mg twice daily for 7 to 10 days.
   Children 7-10 years: 1g once a day for 3 days.
   Children 3 - 7 years – 600mg-800mg once daily for 3 days.
   Children 1-3 years: 500mg once daily for 3 days. Or 15-40mg/kg/day divided in two to three doses.
7. **Treatment of infections of the gums** (for 3 days) or teeth (for 3-7 days)
   Adults and children over 10 years: 200mg three times a day.
8. **Treatment of infected leg ulcers or pressure sores** (for 7 days)
   Adults and children over 10 years: 400mg three times a day
   Treatment of stomach ulcers caused by Helicobacter pylori to be taken as directed by your doctor as part of a course with two other medicines.
9. **Prevention of infections after surgery**
   Adults: 1g as a single dose 24 hours before surgery then, 400mg at 8 hourly intervals during the 24 hours before the operation.
   Children under 12 years: 20-30mg/kg as a single dose 1-2 hours before the operation.
   Newborns with a gestation age less than 40 weeks: A more suitable dosage form should be used.
   Note: If you are elderly or have liver disease, it is particularly important to take this medicine exactly as directed by the doctor.

UNDESIRABLE EFFECTS:
Metronidazole may cause headache, malaise, transient rashes, anorexia, nausea and gastro-intestinal disturbances. Consumption of alcohol increases nausea. The urine of patients taking large doses of the drug may be stained reddish-brown by a pigment that is yet to be positively identified. The pigment is almost certainly a metabolite of metronidazole and seems to have no clinical significance.

CAUTIONS, WARNINGS AND PRECAUTIONS:
Alcohol should be avoided as it may provoke confusion or acute psychoses when used in association with metronidazole. Metronidazole should be used with caution in nursing mothers, in patients with central nervous system diseases, severe obstructive hepatic disease, alcoholic cirrhosis or severe renal dysfunction and those on lithium treatment. Abnormal neurologic signs such as peripheral neuropathy characterised mainly by numbness or paresthesia of an extremity, or ataxia or convulsive seizures may be observed in some patients on metronidazole and in such cases treatment should be withdrawn immediately. It should not be given to patients on disulfiram or those that have been on disulfiram treatment within the last 14 days.

CONTRA-INDICATIONS:
First trimester of pregnancy and in patients with a history of hypersensitivity to metronidazole or nitroimidazole derivatives.

DRUG INTERACTIONS:
Metronidazole potentiates anticoagulant effect of warfarin and other coumarin anticoagulants. Drugs that induce microsomal liver enzymes such as phenytoin or phenobarbitone will accelerate elimination of metronidazole resulting in reduced plasma concentrations while those drugs that decrease the activity of the enzymes such as cimetidine will have the opposite effect.

PHARMACOLOGY:
Pharmacodynamic Properties:-
Metronidazole is a 5-nitroimidazole derivative with a fairly broad antimicrobial activity. Metronidazole has cidal activity against anaerobic protozoa which includes *Balantidium coli, Blastocystis hominis, Trichomonas vaginalis, Entamoeba histolytica, Giardia intestinalis* (formerly *G lamblia)* and the causative organisms of acute ulcerative gingivitis. Metronidazole has bactericidal activity against all obligate anaerobic bacteria and some facultative anaerobic bacteria. Clostridia and susceptible strains of Eubacterium are among the anaerobic Gram-positive bacilli sensitive to metronidazole. Anaerobic Gram-positive cocci sensitive to metronidazole include Peptococci and Peptostreptococci. The facultative anaerobes that are sensitive to metronidazole are *Gardnerella vaginalis*, *Helicobacter pylori* and some spirochaetes.
Pharmacokinetic Properties:
Metronidazole is completely and promptly absorbed when given orally, the plasma concentration having a linear relationship with the dose for doses between 200 - 2000mg. About 10% of the metronidazole is bound to plasma proteins. It has a half-life of about 8 hours in the plasma and repeated doses every 6 to 8 hours results in some accumulation. It is widely distributed in the body and penetrates well into most body tissues and fluids, which include vaginal secretions, seminal fluid, saliva, breast milk and cerebrospinal fluid. Over 50% of systemic metronidazole is metabolized in the liver into two major metabolites both of which have antitrichomonal activity. A good percentage of the drug is excreted unchanged in urine.
Metronidazole is thought to be concentrated in susceptible cells and organisms into chemically reactive reduced forms, which give rise to cytotoxic products. Reduced forms of metronidazole have been shown to cause loss of helical structure and strand breakage in DNA thus impairing its function. Mutagenic effects of metronidazole and its ability to potentiate the effects of radiation on hypoxic tumor cells is probably due to the reduced forms.
LEGAL CATEGORY: Prescription Only Medicine (POM).
THERAPEUTIC CATEGORY: ATC: P01A (Amoebicide and J01K other anti-infective)
STORAGE CONDITIONS: Store in a dry place below 30°C. Protect from light and Keep out of reach of children.
SHELF LIFE: As per the product label.
PRESENTATION:
Tricozole tablets are available in blister pack of 10 x 10's in unit box and bulk packs of 500 and 1000 tablets in securipack opaque plastic containers
Tricozole suspension is available in 60ml and 100ml quantities in amber coloured bottles in a unit box.
DATE OF LAST REVIEW: July 2017

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LTT002-01