1.6 Product Information

1.6.1 Prescribing information (Summary of Product Characteristics)

1. Name of the medicinal product

Tricozole Tablets

2. Qualitative and quantitative composition

Each tablet contains: Metronidazole BP 250mg

3. Pharmaceutical form

Tablets

4. Clinical Particulars

4.1 Therapeutic Indications

Metronidazole is used in the treatment of trichomoniasis and ariicablasis and in the prophylaxis and treatment of anaerobic bacterial infections. It has activity against Trichornonas vaginalis, Entamoeba histolytica, Giardia lamblia and the causative organisms of acute ulcerative gingivitis.

Trichomoniasis: Metronidazole is given by mouth in a dosage of 250mg 3 times a. day for 7 days. Children may be given 10 to 15 mg per kg body weight daily in divided doses. i)

Amoebiasis: : ‘ For treatment of intestinal and hepatic infections with Entamoeba histolytica; Metronidazole is given in a dosage of 400 mg to 1 g 3 times a day for 5 to 7 days. Children may be given 35mg to 50mg per kg body weight daily in divided doses.

Anaerobic infections:

Metronidazole is used alone or in conjunction with other antimicrobials in treatment of infections involving susceptible anaerobic organisms. It is also used to prevent post-operative anaerobic infections after surgery. The usual adult dose by mouth is 500 mg 3 times a day for at least 7 days; the corresponding dose for children-is 3.7 to 7.5 mg per kg body weight every 8 hours.

4.2 Posology and method of administration

Posology

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4.3 Contraindications

First trimester of pregnancy and patients with history of hypersensitivity to metronidazole of Nitroimidazole derivatives.

4.4 Special Warnings and Precautions for Use

Regular clinical and laboratory monitoring (especially leucocyte count) are advised if administration of Metronidazole for more than 10 days is considered to be necessary and patients should be monitored for adverse reactions such as peripheral or central neuropathy (such as paraesthesia, ataxia, dizziness, convulsive seizures).

There is the possibility that after Trichomonas vaginalis has been eliminated a gonococcal infection might persist.

The elimination half-life of metronidazole remains unchanged in the presence of renal failure. The dosage of metronidazole therefore needs no reduction. Such patients however, retain the metabolites of metronidazole. The clinical significance of this is not known at present.

In patients undergoing haemodialysis, metronidazole and metabolites are efficiently removed during an eight-hour period of dialysis. Metronidazole should therefore, be re-administered immediately after haemodialysis.

4.5 Interaction with other medicinal products and other forms of Interaction

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

4.6 Pregnancy and Lactation

There is inadequate evidence of the safety of metronidazole in pregnancy. Metronidazole should not therefore be given during pregnancy or during lactation unless the physician considers it essential, in these circumstances short, high dosage regimes are not recommended.

A significant amount of metronidazole is found in breast milk and breast feeding should be avoided after a large dose. This could give a bitter taste to the milk.

4.7 Effects on Ability to Drive and Use Machines

None unknown

4.8 Undesirable Effects

4.9 Patients should be warned about the potential for drowsiness, dizziness, confusion, hallucinations, convulsions or transient visual disorders, and advised not to drive or operate machinery if these symptoms occur

4.10 Overdose and treatment

Below are the symptoms of overdose

- Nervous system effects, including seizures and encephalopathy (abnormal brain function).

Symptoms can include:

- Convulsions (sudden movements caused by tightening of your muscles)
- Dizziness
- Headache
- Confusion
- Ataxia (loss of control of body movements**)**

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: P01AB01

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, Glardia 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.

5.2 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 6-8 hours results in some accumulation. It is widely distributed in the body and penetrates well into most body tissues and fluids, which include vagina secretions, seminal secretions, saliva, breast milk and celebralspinal fluid. Over 50% if 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 tumour cells is probably due to the reduced forms

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

- White corn starch
- Tartrazine colour (Water Soluble)
- Lactose Monohydrate
- White corn starch (For Paste)
- Potassium Sorbate
- Gelatin
- Colloidal Silicon Dioxide (Aerosil 200)
- Purified Talcum

6.2 Incompatibilities

None known.

6.3 Shelf Life

36 months from the date of manufacture

6.4 Special Precautions for Storage

Store below 30°C in a dry place.

6.5 Nature and Contents of Container

Yellow, circular, FFBE tablets scored on one side and plain on reverse. Packed in 1000's in HDPE container with literature insert & in 10x 10's in unit boxes.

6.6 Special precaution for disposal and other handling

Not applicable

7 Marketing Authorization Holder and Manufacturing Site Addresses

Marketing Authorization Holder:

Company Name: LABORATORY & ALLIED LTD

Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road, P.O. Box 42875 GPO 00100, Nairobi,

Country : Kenya

Telephone : +254 20 8040306

Telefax : +254 20 8040309

E-Mail : info@laballied.com.

TRICOZOLE TABLETS
(METRONIDAZOLE 250MG)

MODULE 1	:	ADMINISTRATIVE INFORMATION & PRODUCT INFORMATION

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