SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENERIC: Metronidazole Oral Suspension BP 125mg/5mL

BRAND NAME: METROKANT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL of suspension on reconstitution contains:

Metronidazole Benzoate BP equivalent to

Metronidazole…….....……125 mg

Excipients …….q.s.

Colour: Sunset yellow

3. PHARMACEUTICAL FORM:

Liquid, Oral Dosage Form – Suspension.

Orange Color viscous suspension.

4.CLINICAL PARTICULARS

4.1 Therapeutic Indication:

Treatment of protozoal infections such as amoebiasis, balantidiasis blastacystis hominis infections, giardiasis and trichomoniasis. Treatment and prophylaxis of anaerobic bacterial infections & sensitive to Metronidazole.

4.2 Posology and method of administration:

Adults and children over 12 years:

Anaerobic bacterial infections: An initial dose of 800mg followed by 400mg three times a day for 7 days.

Amoebiasis, balantidiasis and blastocytis hominis infection:400-800mg three times a day for 5-10 days.

Giardiasis: 2g once daily for 3 successive days.

Trichomoniasis infection: 250mg three times a day for 7 days OR As directed by the physician.

Children below 12 years:

Anaerobic bacterial infections: The usual dose is 7.5mg/kg body weight every 8 hours for 7 days.

Amoebiasis and balantidiasis infections: 35-50mg/kg body weight daily in divided doses for 5-10 days.

Giardiasis: 15mg/kg body weight daily in divided doses for 5 days.

Method of administration: Oral.

4.3 Contraindications:

It is contra-indicated in patients with a prior history of hypersensitivity to Metronidazole or other nitroimidazole derivatives. Metronidazole should also be avoided in patients with a history of serious neurologic disease, including seizures and in patients with severe liver disease.

4.4 Warning and precautions for use

Doses should be reduced in patients with severe liver disease. Intake of alcoholic beverages should be avoided during treatment with Metronidazole.

4.5 Drug Interactions

Concomitant use of alcoholic beverages should be avoided because this may provoke acute psychoses or confusion. Metronidazole can impair the metabolism or excretion of Warfarin, Phenytoin, Lithium and Fluorouracil with the consequent potential for an increased incidence of adverse effects.

Plasma concentrations are decreased by the concomitant use of Phenobarbitone. Cimetidine can increase the plasma concentrations and might increase the risk of neurological side effects.

4.6 Fertility Pregnancy & Lactation

Metronidazole should not be given during pregnancy or during lactation unless the physician considers it essential.

4.7 Effects on ability to drive and use machines:

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.

4.8 Adverse Effects

The side effects include gastro-intestinal discomfort, anorexia, nausea, coated tongue, dryness of the mouth and an unpleasant taste, headaches and skin rashes and, less frequently, vertigo, depression, insomnia, drowsiness, urethral discomfort and darkening of the urine. There may be a temporary decrease in the total white cell count.

4.9 Overdose

Single oral doses of metronidazole, up to 15g, have been reported in suicide attempts and accidental overdoses. Symptoms reported include nausea, vomiting, and ataxia.

There is no specific antidote for overdose; therefore, management of the patient should consist of symptomatic and supportive therapy.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Metronidazole has antiprotozoal and antibacterial actions including activity against anaerobic bacteria and entamoeba histolytica.

5.2 Pharmacokinetic properties

A nitroimidazole derivative well absorbed and widely distributed in the body. It is metabolised by hepatic acid oxidation, hydroxylation and glucuronidation and excreted in urine and faeces with a T½ of about 6-10 hours.

These slight differences in the rate and extent of metronidazole absorption are due to the transformation of metronidazole benzoate to the active compound metronidazole by hydrolysation in the gastrointestinal tract.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose (sugar pharmagrade), Xanthan Gum, Sorbitol Solution 70% (Non-crystallizing), Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate, Sodium Benzoate, Sodium Saccharin, Carmellose Sodium, Colloidal Anhydrous Silica, Polysorbate 80 (Tween 80), Citric Acid Anhydrous, Colour Sunset Yellow FCF Supra, Flavour mixed Fruit, Bronopol, Purified water**.**

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months

6.4 Special precautions for storage:

Store at a temperature not exceeding 30°C, in a dry place. Protect from light.

Keep the medicine out of reach of children.

6.5 Nature and contents of container

100 ml Amber colour PET bottle with 25mm cap in a carton along with the Insert.

7. APPLICANT
Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,
Vapi - 396 195. Gujarat, INDIA.

8. NATIONAL REGISTRATION NUMBER

07262/09514/NMR/2022

9. DATE OF AUTHORISATION

11/04/2022

10. DATE OF REVISION OF THE TEXT

July 2023