Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

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Metronidazole Oral Suspension 125 mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml after reconstitution contains:

Metronidazole Benzoate BP

Eq. to Metronidazole 125 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for Suspension

White to off-white granular powder forming orange coloured suspension after reconstitution with water.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

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 3 times daily for 7 days.

Amoebiasis, balantidiasis and blastocytis hominis infection: 400-800mg 3 times daily for 5-10 days.

Giardiasis: 2g once daily for 3 successive days.

Trichomoniasis infection: As directed by the physician.

Children:

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.

Route of administration: oral.

4.3 Contraindications

Metronidazole is contraindicated in patients with a prior history of hypersensitivity to Metronidazole or other Nitroimidazole derivatives. In patients with trichomoniasis, Metronidazole is contraindicated during the first trimester of pregnancy.

4.4 Special warnings and precautions for use

It should be used with caution in patients with severe hepatic diseases due to the risk of accumulation of Metronidazole and its metabolites. Alcoholic beverages should be avoided while taking Metronidazole and for at least one day after treatment.

4.5 Interaction with other medicinal products and other forms of interact.

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 and Lactation

Metronidazole is secreted in breast milk in concentrations similar to those found in plasma. Please consult your physician for advice for use of Metronidazole during pregnancy and breast-feeding.

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 Undesirable effects

The side effects are dose related and moderate. The most common are: Gastro-intestinal disturbances, especially nausea and a metallic taste. Vomiting, diarrhoea or constipation may also occur.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Symptoms of overdosage are limited to vomiting, ataxia and slight disorientation.

There is no specific treatment for gross overdosage of metronidazole. Treatment should be symptomatic and supportive.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Metronidazole is an antimicrobial drug that is primarily active against obligate anaerobic microorganisms, both bacteria and protozoa. The 5-nitro group undergoes reductive transformation to an active intermediate which then exerts an inhibitory or lethal effect against DNA. Not only is DNA synthesis inhibited but the reduced metabolite also cause a loss of the helical structure of DNA with subsequent DNA strand breakage. The structure of the intermediate has not been determined. Other reduction oxidation processes within anaerobic organisms may also be inhibited, which also contribute to cell death. In vitro, Metronidazole demonstrates a consistently rapid bactericidal effect with the minimal bactericidal concentration approximating very closely to the minimal inhibitory concentration.

5.2 Pharmacokinetic properties

Metronidazole is rapidly absorbed after oral administration of drug with peak plasma concentrations occur after 20 min to 3 hours.

The elimination half-life of Metronidazole is 7 to 8 hours. Metronidazole is excreted in milk but the intake of a suckling infant of a mother receiving normal dose would be considerably less than the therapeutic dosage for infants.

5.3 Preclinical safety data

None stated.

6.0 Pharmaceutical particulars

6.1 List of excipients

Xanthan Gum, Colloidal Anhydrous Silica, Disodium Edetate, Sodium Chloride, Sodium Methyl Hydroxybenzoate, Citric Acid Monohydrate, Anhydrous Disodium Hydrogen Phosphate, Saccharin Sodium, Sunset Yellow, Orange Flavour and Sucrose.

6.2 Incompatibilities

None reported

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. Use the reconstituted oral suspension within 7 days of preparation.

6.5 Nature and contents of container

100 ml HDPE bottle and ROPP cap.

6.6 Special precautions for disposal and other handling

Keep this medicine out of the reach and sight of children. This medicine must not be used after the date (Exp) printed on the pack. Return any leftover medicine to your pharmacist.

7. Marketing Authorisation Holder

MEDICAMEN BIOTECH LIMITED

SP-1192 A & B, Phase-IV,
Industrial Area, Bhiwadi-301019,
Distt Alwar, Rajasthan India

8. Number(s) in the national register of finished pharmaceutical products

Certificate No: 08438/09707/NMR/2022

9. Date of first authorisation/renewal of the authorisation

Mar 1, 2023

10. Date of revision of the text

August 2023