SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
METRON-F (Metronidazole & Furazolidone Oral Suspension)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 5 ml. contains:

Metronidazole Benzoate BP	
Equivalent to Metronidazole	100 mg
Furazolidone BP	30 mg
Flavoured Syrupy Base	q.s.

Colour: Approved colour used.

3. PHARMACEUTICAL FORM:
Yellow coloured, homogeneous suspension having Bitter Mask flavour.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications:
Metronidazole
1.Amoebiasis
2.Giardiasis
3.Trichomonas vaginitis
4.Pseudo membranous enterocolitis
5.Anaerobic bacterial infections after surgery, Brain abscess, & Endocarditis
6.Helicobacter pylori infections
7.Ulcerative gingivitis

Furazolidone
1. Bacterial diarrhoea
2. Protozoal diarrhoea
3. Enteritis
4. Giardiasis
5. Trichomoniasis
6. Food poisoning
7. Infections caused by salmonella shigella etc.
8. Bacterial and monilial vaginitis

4.2 Posology and Method of Administration:
Posology
Metronidazole
Adult
Amoebiasis:400 to 800 mg 8hourly for 5 to 10days depending up on the severity of infection
In severe infections and liver abscess: 1gm as slow I.V. infusion followed by 0.5 gm twice daily till oral therapy is started
Giardiasis:200mg 8hourly for 1week or 2gm/day for 3days or I.V.500mg thrice daily
Trichomonas vaginitis: 400mg 8 hourly for a week or 2gm once daily for a week.

Male partner should be concurrently treated with the drug
Pseudo membranous enterocolitis:800 mg 8hourly
Anaerobic bacterial infections after surgery, Brain abscess, & Endocarditis:400 to 800 mg 8hourly
In severe cases: 15mg/kg I.V. infusion for 1hour followed by 7.5mg/kg 4 times daily till oral therapy is substituted
Helicobacter pylori infections:400mg 8hourly along with amoxicillin/clarithromycin and a proton pump inhibitor
Ulcerative gingivitis:200 to 800mg 8hourly
Children
Amoebiasis: 30 to 50mg/kg/day for 5to10 days.
Giardiasis:10 to 15mg/kg/day thrice daily

Furazolidone
Adults: 100mg 6 hourly 2 to 7 days depending up on the severity of infections
Children: 1.25 mg 6 hourly for 2 to 5 days & up to 10days for Giardiasis

Method of administration
Oral use.

4.3 Contra – Indications:

Metronidazole
1. Hypersensitivity to the drug
2. Blood dyscrasias
3. CNS disorders

Furazolidone
1. Hypersensitivity
2. Along with alcohol

4.4 Special Warning and Precautions for Use:

Metronidazole
1. Renal impairment
2. Hepatic impairment
3. Alcoholic cirrhosis
4. Use cautiously along with other hepatotoxic drugs & In visual field changes

Furazolidone
1. Use cautiously in G6PD deficiency
2. Urine colour turns orange which has no clinical significance

4.5 Interaction with other medicinal products and other forms of interaction

Metronidazole
Warfarin & other coumarin anticoagulants: Potentiates the anticoagulant effect resulting in increased prothrombin time.
Alcohol: A disulfiram-like reaction. Abdominal cramps, nausea, vomiting, headache & flushing.
Disulfiram: Acute psychotic reaction or confusional state.
Phenobarbital & Phenytoin: Increased metabolism of metronidazole resulting in decreased efficacy.
Lithium: Increased lithium levels and toxicity.
Flurouracil: Increased toxicity of flurouracil.

Lab tests: May interfere with chemical analysis for AST,SGOT, ALT, SGPT, LDH, triglycerides and hexokinase glucose. Zero values may occur.

Furazolidone

Alcohol: Disulfiram like reaction-facial flushing,light headedness, weakness, lacrimation.
Anorexiants: Increased pressor response of anorexiants due to MAO inhibition.
Levodopa: Both efficacy and adverse effects of levodopa increased especially hypertensive crisis. Effect lasts for several weeks after stopping furazolidone.
Sympathomimetics (indirect & mixed): Increased pressor sensitivity to these agents due to MAO inhibition.
TCAs: Hypertension, hyperpyrexia, seizures, tachycardia, acute psychosis.
Hypnotics & Sedatives: Dose of hypnotics and sedatives should be reduced.
Hypoglycaemics: Potentiates them.
Food: Hypertensive crisis with tyramine containing foods.

4.6 Pregnancy and lactation

Metronidazole

During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.

Furazolidone

The safety of Furazolidone during the childbearing age has not been established; as with any potent antibacterial, furazolidone must be administered with caution during the childbearing age. However, animal breeding studies have revealed no evidence of teratogenicity following the administration of furazolidone for long periods of time and at doses far in excess of those recommended for the human. There have been no clinical reports regarding this possible adverse effect on the fetus or the newborn infant.

4.7 Effects on ability to drive and use machine:

Effects on ability to drive and use machine is not reported.

4.8 Undesirable effects

Metronidazole

1.Anorexia.
2.Metallic taste
3.Nausea
4.Vomiting
5.Diarrhoea
6.Headache
7.Looseness of stool.
8.Peripheral neuropathy &CNS effects.
9.Mutagenesis.
10.Radiosensitisation.
11.Transient leucopenia
12.Dry mouth
13.Abdominal distress
14.Dizziness
15.Vertigo
16.Thrombophlebitis at site of injection
17.Ototoxicity

Furazolidone

1. Dizziness
2. Headache
3. Nausea
4. Vomiting
5. Decreased B.P
6. Deafness with tinnitus
7. Urticaria
8. Fever
9. Arthralgia
10. Disulfiram like reactions with alcohol.

4.9 Overdoses:

Metronidazole

Treatment is supportive & symptomatic. Drug is removed by induced emesis, gastric lavage, and administration of activated charcoal & use of cathartics. For controlling seizures diazepam & phenytoin may be used.

Furazolidone

Treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

Metronidazole

Metronidazole is nitro imidazoles which have broad spectrum cidal activity against Protozoa and some anaerobic bacteria. Its selective toxicity to anaerobic microbes involves 1. Drug enters the cell by diffusion, 2. Nitro group of drug is reduced by redox proteins present only in anaerobic organisms to reactive nitro radical which exerts cytotoxic action by damaging DNA and other critical biomolecules. 3. DNA helix destabilization & strand breakage has been observed.

Furazolidone

Furazolidone is a nitro furan which is employed as a broad spectrum bactericidal agent the actual mechanism of action is not clear. But it is known that it interfere with several bacterial enzyme systems. They have effects on DNA and bring about various changes in bacteria & also have radiomimetic & mutagenic properties.

5.2 Pharmacokinetic properties

Metronidazole

Absorption: Well absorbed orally, Distribution: Widely distributed,
Metabolism: Metabolized in liver by oxidation & glucuronide conjugation, Excretion: Excreted in urine.

Furazolidone

Absorption: It is partially absorbed orally
Excretion: It is excreted in urine

5.3 Preclinical safety data

Not available.

6. FURTHER INFORMATION

What METRON-F contains:

- The active pharmaceutical ingredients are Metronidazole & Furazolidone.
- The other ingredients are Methyl Paraben, Propyl Paraben, Sodium Benzoate, Di-Sodium Hydrogen Phosphate, Sucrose, Polysorbate 80, Aerosil (Silicone Dioxide), Sorbitol Solution 70% (Non Crystalising), Xanthan Gum (Plain), Arrowcell CRT / Arrow Gum Super, Guar (Delca-P 225), Sodium Hydroxide, Enisweet EP Powder, Colour Tartrazine Supra, Bitter Mask No. 1 Flavour, Pineapple M-452 Flavour, Purified water.

What METRON-F looks like and contents of the pack:
Yellow coloured, homogeneous suspension having Bitter Mask flavour.

Primary Packing: 100 ml Bottle.
Secondary Packing: Such 1 Bottle is place in a carton along with pack insert.

7. Marketing Authorization number and Manufacturing Site Address
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8. Marketing Authorization number
FDA/SD.245-091628

9. Date of first Authorization/renewal
September 2024

10. Date of revision of text
July 2025