1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC) - Enclosed

SHALMET 400

(Metronidazole Tablets BP 400 mg)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SHALMET 400 (Metronidazole Tablets BP 400 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Approved Name (if any)	Quantity / Tablet (mg)	Active / Non - active
Metronidazole BP	400.00	Active Ingredient
Excipients		
Dibasic calcium phosphate dehydrate BP	15.00	Diluent
Sodium starch glycolate BP	10.00	Disintegrant
*Maize starch BP	25.00	Diluent
*Maize starch (for paste) BP	19.00	Binder
Sodium benzoate BP	1.00	Preservative
LUBRICATION		
Maize starch BP	7.00	Glidant
Colloidal Anhydrous silica (Aerosil) BP	3.00	Glidant
Purified Talc BP	2.00	Lubricant
Magnesium stearate BP	3.00	Disintegrant
COATING MATERIAL		
#Instacoat EHP- 250 (A10R20499) Yellow INH (Composition: Polyvinyl Alcohol BP, Glycerol monostearate USP/ NF, Polysorbate 80 BP, Triacetin BP, Talc BP, Modified starch USP/NF, Titanium dioxide BP, Lake quinolone yellow, Yellow Iron Oxide, Lake sunset yellow)	15.00	Film coating

*Include 8.0% extra to compensate for LOD. Maize starch included = 0.530 kg

#20% Overages taken extra for coating process loss

Definitions:

BP: British Pharmacopoeia

USP: United Stats Pharmacopoeia

IH: In-House Specifications

3. PHARMACEUTICAL FORM

Tablets (Oral)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of septicaemia, bacteraemia, brain abscess, necrotising pneumonia, osteomyelitis, puerperal sepsis, pelvic abscess, pelvic cellulitis, peritonitis and post-operative wound infections.

• The prevention of post-operative infections caused by anaerobic bacteria.

• Bacterial vaginosis; The treatment of urogenital trichomoniasis; Giardiasis;

• Acute dental infections; Acute ulcerative gingivitis.

• All forms of amoebiasis; Anaerobically infected leg ulcers and pressure sores.

4.2 Posology and method of administration

Prophylaxis against anaerobic infection- abdominal and gynaecological surgery.

• Dosage: 400mg at 8 hourly intervals during the 24 hours preceding the operation followed by postoperative intravenous administration until the patient is able to take oral Metronidazole.

• Children < 12 years: 20 – 30mg/kg as a single dose given 1 – 2 hours before surgery.

• Newborns with a gestation age <40 weeks: 10mg/kg body weight as a single dose before operation.

• Elderly: Caution is advised in the elderly, particularly at high doses.

Treatment of established anaerobic infection:

• Adults: 800mg followed by 400mg at 8 hourly intervals.

• Children > 8 weeks to 12 years of age: 20 – 30mg/kg/day as a single dose or divided into 7.5mg/kg every 8 hours. The daily dose may be increased to 40mg/kg, depending on the severity of the infection. Duration of treatment is usually 7 days.

• Children < 8 weeks of age: 15mg/kg as a single dose daily or divided into 7.5mg/kg every 12 hours.

• In newborns with a gestation age <40 weeks, concentrations of metronidazole in serum should preferably be monitored after a few days therapy.

• Treatment of protozoal and other infections.

Urogenital Trichomoniasis: Adults and children over 10 years: 200mg three times daily for 7 days or 400mg twice daily for 5-7 days or 2000mg as a single dose

Children 1 – 10 years: 40mg/kg orally as a single dose or 15 – 30mg/kg/day divided in 2 – 3 doses not to exceed 2000mg/dose.

Bacterial Vaginosis: Adults and children over 10 years: 400mg twice daily for 7 days or 2000mg as a single dose.

Amoebiasis: Invasive intestinal disease in susceptible subjects. Adults and children over 10 years: 800 mg three times daily for 5 days. Children 1 – 3 years: 200 mg three times daily; Children 3 – 7 years: 200 mg four times daily.

Children 7 – 10 years: 400 mg three times daily.

Intestinal disease in less susceptible subjects and chronic amoebic hepatitis: Adults and children over 10 years: 400mg three times daily for 5 – 10 days. Children 1 – 3 years: 100mg three times daily for 5 – 10 days; Children 3 – 7 years: 100mg four times daily for 5 – 10 days; Children 7 – 10 years: 200mg three times daily for 5 – 10 days.

Amoebic liver abscess: Adults and children over 10 years: 400mg three times daily for 5 days. Children 1 – 3 years: 100mg three times daily for 5 days; Children 3 – 7 years: 100 mg four times daily for 5 days; Children 7 – 10 years: 200mg three times daily for 5 days.

Symptomless cyst passers: Adults and children over 10 years: 400-800mg three times daily for 5-10days. Children 1 – 3 years: 100-200 mg three times daily for 5-10 days; Children 3 – 7 years: 100 - 200mg four times daily for 5-10 days; Children 7 – 10 years: 200 -400mg three times daily for 5-10days.

Giardiasis: Adults and children over 10 years: 2000mg once daily for 3 days or 400mg three times daily for 5 days or 500mg twice daily for 7 – 10 days. Children 1 – 3 years: 500mg once daily for 3 days; Children 3 – 7 years: 600 - 800mg once daily for 3 days. Children 7 – 10 years: 1000 mg once daily for 3 days;

Acute Ulcerative Gingivitis: Adults and children over 10 years: 200mg three times daily for 3 days. Children 1 – 3 years: 50mg three times for 3 days; Children 3 – 7 years: 100mg twice daily for 3 days. Children 7 – 10 years: 100mg three times daily for 3 days.

Acute Dental Infections: Adults and children over 10 years: 200mg three times daily for 3 – 7 days.

Leg Ulcers and Pressure Sores: Adults and children over 10 years: 400mg three times daily for 7 days.

Children and infants weighing less than 10kg should receive proportionally smaller dosages.

Method of administration: Oral use.

4.3 Contraindications

Metronidazole Tablets contraindicated in the conditions:

- Known hypersensitivity to Metronidazole, nitroimidazoles and/or hydroxybenzoates or any of the component of the formulation.
- Patients who have taken disulfiram within the last two weeks.
- Consumption of alcohol or products containing propylene glycol during and for at least three days after therapy with metronidazole.

4.4 Special warnings and precautions for use

Metronidazole should be re-administered immediately after haemodialysis; Substantial impairment of metronidazole clearance may occur in the presence of advanced hepatic insufficiency; Administer with caution to patients with hepatic encephalopathy. The daily dosage may be reduced to one third and may be administered once daily; Use with caution in patients with active or chronic severe peripheral and central nervous system disease; If symptoms or signs of Stevens Johnson syndrome, toxic epidermal necrolysis or acute generalised exanthematous pustulosis are present, treatment with metronidazole must be immediately discontinued; Patients with Cockayne syndrome should be advised to immediately report any symptoms of potential liver injury to their physician and stop taking metronidazole.

4.5 Interaction with other medicinal products and other forms of interaction

Dosage of the anticoagulant may require reducing and prothrombin time should be monitored. No interactions have been reported of the heparin type; Lithium treatment should be tapered or withdrawn before administering metronidazole; Co-administration with phenobarbital or phenytoin reduces the half-life of metronidazole to approximately three hours; Increased serum carbamazepine levels and toxicity have been seen in patients given concomitant metronidazole; Aspartate amino transferase assays may give spuriously low values in patients taking metronidazole, depending on the method used; Metronidazole reduces the clearance of 5-fluorouracil and can therefore result in increased toxicity of 5-fluorouracil; Serum ciclosporin / tacrolimus and serum creatinine should be closely monitored when coadministration is necessary; Plasma levels of busulfan may be increased by metronidazole which may lead to severe busulfan toxicity.

4.6 Pregnancy and 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

Not applicable.

4.8 Undesirable effects

Metronidazole is generally well tolerated however, side effect of unknown frequency includes urticaria, angioedema, fever, anorexia, depressed mood, peripheral neuropathy or transient epileptiform seizures, optic neuropathy/neuritis, hearing impairment, unpleasant taste in the mouth, oral mucositis, furred tongue, nausea, vomiting, gastro-intestinal disturbances such as epigastric pain and diarrhoea.

4.9 Overdose

Single oral doses of metronidazole, up to 12g have been reported in suicide attempts and accidental overdoses. Symptoms were limited to vomiting, ataxia and slight disorientation. In cases of suspected massive overdose, symptomatic and supportive treatment should be instituted.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological category: Antiprotozoal and Antibacterial.

ATC Code: J01X D01

5.1 Pharmacodynamic properties

Metronidazole has antiprotozoal and antibacterial actions. Inhibits DNA synthesis leading to death of bacteria.

Spectrum of action.

Gram-positive anaerobes: Clostridium species, Eubacterium species, Peptococcus species and Peptostreptococcus species

Gram-negative anaerobes: Bacteroides fragilis group (B. fragilis, B. distasonis, B. ovatus, B. thetaiotaomicron, B. vulgatus) Fusobacterium species.

Protozoal parasites: Entamoeba histolytica, Trichomonas vaginalis.

5.2 Pharmacokinetic properties

Metronidazole is readily absorbed from the gastro-intestinal tract and widely distributed in body tissues. It penetrates well into body tissues and fluids. The half-life in plasma is about 8-10 hours. Unchanged metronidazole and several metabolites are excreted in the urine.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibasic Calcium Phosphate Dihydrate BP, Maize Starch BP, Sodium Benzoate BP, Sodium Starch Glycolate BP, Colloidal Anhydrous Silica BP, Purified Talc BP, Magnesium Stearate BP, Polyvinyl Alcohol BP, Glycerol Monostearate USP/NF, Polysorbate 80 BP, Triacetin BP, Modified Starch USP/NF, Colour: Yellow Iron Oxide USP/NF, Lake Quinoline Yellow, Lake Sunset Yellow and Titanium Dioxide BP.

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

Blister pack of 10 Tablets. Such 10 filled blister are packed in a printed inner carton along with a leaflet & such 10 inner cartons are packed in outer carton.

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC,

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

8. MARKETING AUTHORISATION NUMBER

Application for granting new registration certificate

9. DATE OF FIRST AUTHORISATION

Application for granting new registration certificate

10. DATE OF UPDATE OF TEXT

October 2022