NAPO VAG-M
Miconazole Nitrate Vaginal Soft Gelatin Capsules 400 mg

COMPOSITION:
Each Vaginal Soft Gelatin Capsule Contains:
Miconazole Nitrate BP 400 mg
Excipient q.s.
Approved colours used in soft gelatin capsule shell.

PHARMACODYNAMICS:
Pharmacotherapeutic classification: Anti-infectives and antiseptics
ATC code: G01A F04
Miconazole combines a potent antifungal activity against common dermatophytes and yeasts with an antibacterial activity against certain gram-positive bacilli and cocci.
Miconazole inhibits the biosynthesis of ergosterol in fungi and changes the composition of other lipid components in the membrane, resulting in fungal cell necrosis.
In general, miconazole exerts a very rapid effect on pruritus, a symptom that frequently accompanies dermatophyte and yeast infections.

PHARMACOKINETIC:
Absorption: Miconazole persists in the vagina for up to 72 hours after a single dose. Systemic absorption of miconazole after intravaginal administration is limited, with a bioavailability of 1 to 2% following intravaginal administration of a 1200 mg dose. Plasma concentrations of miconazole are measurable within 2 hours of administration in some subjects, with maximal levels seen 12 to 24 hours after administration. Plasma concentrations decline slowly thereafter and were still measurable in most subjects 96 hours post-dose. A second dose administered 48 hours later resulted in a plasma profile similar to that of the first dose.
Distribution: Absorbed miconazole is bound to plasma proteins (88.2%) and red blood cells (10.6%).
Metabolism and Excretion: The small amount of miconazole that is absorbed is eliminated predominantly in faeces as both unchanged drug and metabolites over a four-day post-administration period. Smaller amounts of unchanged drug and metabolites also appear in urine. The apparent elimination half-life ranges from 15 to 49 hours in most subjects and likely reflects both absorption from the site and metabolism/excretion of the drug.

THERAPEUTIC INDICATIONS:
For the local treatment of vulvovaginal candidosis and superinfections due to gram-positive bacteria.

POSOLOGY AND METHOD OF ADMINISTRATION:
Route of Administration: Oral
Use once daily before bedtime, insert one capsule deeply into the vagina. This is best done in a reclining position and before bedtime. Repeat procedure for 3 days. Treatment can be shortened by begining with one vaginal capsule on the first and continuing with two vaginal capsules (one in the morning, one before bedtime) for the next three days. Complete the enire treatment and dosage even if symptoms have disappeared. Ensure you also adhere to prescription by your Doctor. Treatment should be timed so as to avoid the menstrual period.

CONTRAINDICATION:
NAPO VAG M is contraindicated in individuals with a known hypersensitivity to miconazole/miconazole nitrate, other imidazole derivatives or to any of the excipients

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with miconazole formulations If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.
Appropriate therapy is indicated when the sexual partner is also infected.
The concurrent use of latex condoms or diaphragms with vaginal anti-infective preparations may decrease the effectiveness of latex contraceptive agents.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:
Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after vaginal application, clinically relevant interactions occur very rarely. In patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored. The effects and side effects of other drugs metabolized by CYP2C9 (e.g. oral hypoglycemics and phenytoin) and also CYP3A4 (e.g., HMG-CoA reductase inhibitors such as simvastatin and lovastatin and calcium channel blockers such as dihydropyridines and verapamil), when co-administered with miconazole, can be increased and caution should be exercised.

PREGNANCY AND LACTATION
Pregnancy:
Although intravaginal absorption is limited, Miconazole Nitrate Vaginal Soft Gelatin Capsules should be used in the first trimester of pregnancy only if, in the judgement of the physician, the potential benefits outweigh the possible risks.
Lactation:
It is not known whether miconazole nitrate is excreted in human milk. Caution should be exercised when using Miconazole Nitrate Vaginal Soft Gelatin Capsules during breastfeeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
None known.

ADVERSE REACTION:
Flatulence may occur during the first few days of treatment, it disappears after a couple of days. When dosages higher than instructed are used, abdominal pain and diarrhoea may occur. In such a case the dosage should be decreased.

OVERDOSE:
Symptoms
In case of accidental ingestion, vomiting and diarrhoea may occur.
Treatment
In case of accidental ingestion, the treatment is symptomatic and supportive.

SHELF LIFE:
36 Months

PACKAGING:
3 Soft gelatin capsule are packed in Alu-PVC blister. Such 2 blisters are packed in printed monocarton along with applicator & pack insert; such 10 monocartons are packed in printed outer carton

STORAGE CONDITION:
Store in cool & dry place below 30°C. Protect from direct sunlight, heat and moisture.
Keep the medicine out of reach of children.

FOR EXPORT ONLY
Exported by:

Napo Exports Private Limited
204, Dilpasand Green, Indore (India)
Email: napoexports@gmail.com

ALWAYS BEST EFFICIENT EFFECTIVE RESULT

MANUFACTURED IN INDIA BY :
DR. SMITHS BIOTECH PVT. LTD.
(An ISO 9001:2015 & WHO GMP Certified Co.)
B-5, Khasra No. 9 & 10, Dev Bhoomi Industrial Estate,
Bantakhedi, Roorkee, Distt. Haridwar (Uttarakhand)-247667