ZAMITRO VAGINAL TABLETS

(Clotrimazole 100 mg & 500 mg)

COMPOSITION

Zamitro 100 mg: Each vaginal tablet contains Clotrimazole 100 mg.
Zamitro 500 mg: Each vaginal tablet contains Clotrimazole 500 mg.
Excipients: according to approved formulation.

DESCRIPTION & PHARMACOLOGY

Clotrimazole is an imidazole antifungal agent. It inhibits fungal ergosterol synthesis, disrupting the fungal cell membrane. It acts locally against susceptible Candida species responsible for vulvovaginal candidiasis (vaginal thrush).

INDICATIONS

Local treatment of vulvovaginal candidiasis (candidal vaginitis) caused by susceptible organisms, according to the approved product indication.

DOSAGE & ADMINISTRATION

100 mg strength: Insert one vaginal tablet deeply into the vagina at bedtime for six consecutive nights (six tablets in total).
500 mg strength: Insert one vaginal tablet deeply into the vagina once at bedtime (single-dose treatment).

For vaginal use only. DO NOT SWALLOW. Follow the prescribed course and local approved product instructions.

HOW TO INSERT

Wash hands before and after insertion. At bedtime, remove a tablet from its packaging. While lying on the back with knees bent, gently insert the tablet as deeply as comfortably possible using a supplied applicator if appropriate and permitted by the approved instructions. If no applicator is supplied, follow the package-specific insertion directions.

During pregnancy, insert with a clean finger rather than an applicator, under medical supervision. Vaginal tablets need moisture to dissolve; some residue may be noticed, especially with vaginal dryness.

IMPORTANT USE INSTRUCTIONS

Avoid use during menstruation where possible; complete the treatment before menstruation begins. Do not use tampons, vaginal douches, spermicides or other intravaginal products during treatment. Avoid vaginal intercourse during infection and treatment.

If symptoms do not improve within seven days, worsen, or return repeatedly, seek medical assessment. Recurrent infection may require confirmation of diagnosis and a different regimen.

CONTRAINDICATIONS

Known hypersensitivity to clotrimazole, other imidazole antifungals or any ingredient of the product.

AGE GROUPS

Use in patients under 16 years should be directed by a clinician; refer to the approved local label for age restrictions.

WARNINGS & PRECAUTIONS

Seek medical advice before use if this is the first episode of vaginal symptoms; if infections recur more than twice in six months; if there is a history of sexually transmitted infection; or if pregnancy is suspected.

Seek assessment for fever, lower abdominal pain, painful urination, foul-smelling discharge, vaginal sores, abnormal bleeding, nausea or vomiting, as these may indicate a condition other than thrush.

LATEX CONTRACEPTION

Clotrimazole vaginal products may reduce the effectiveness of latex condoms and diaphragms. Use alternative precautions during treatment and for at least five days afterward.

PREGNANCY & BREASTFEEDING

Clotrimazole may be used during pregnancy under a physician or midwife's supervision. Do not use an applicator during pregnancy. Systemic absorption after vaginal administration is low; use during breastfeeding may be considered after professional advice.

DRUG INTERACTIONS

Tell the clinician if taking tacrolimus or sirolimus, as intravaginal clotrimazole may increase their blood concentrations. Inform the clinician about other medicines and vaginal treatments.

ADVERSE REACTIONS

Possible reactions include local burning, irritation, itching, redness, swelling, pelvic discomfort, rash and vaginal discharge. Rarely, allergic reactions may occur. Stop use and seek immediate help for severe swelling, breathing difficulty or other serious allergy symptoms.

OVERDOSAGE / ACCIDENTAL INGESTION

Excess intravaginal use may increase local irritation. If swallowed accidentally, seek medical advice promptly, especially for children. There is no specific antidote; treatment is supportive.

STORAGE CONDITIONS

Store below 25 degrees C, or according to the approved product storage specifications. Protect from excessive heat and moisture. Keep out of reach of children. Do not use after expiry.

PRESENTATION

Zamitro Vaginal Tablets 100 mg: Pack of 6 vaginal tablets.
Zamitro Vaginal Tablets 500 mg: Pack of 1 vaginal tablet.

PATIENT ADVICE

Use only by the vaginal route. Complete the six-night course for 100 mg or the single-dose course for 500 mg as instructed. Do not share this medicine. If symptoms persist beyond seven days or recur frequently, consult a healthcare professional.

THERAPEUTIC CLASS

Imidazole antifungal (local vaginal antimycotic). Primary medical segment: Gynaecology; secondary: General Practice.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.