

**CLOVIGAL**  
(Clotrimazole Vaginal Tablets)

Nafdac No.A4-0279

**Composition:** **for vaginal use only**

Each uncoated vaginal tablet contains:

Clotrimazole	BP	100mg
Excipients		q.s

Clovigal offers efficient treatment for all vaginal infections caused by candida species, Torulopsis species, Trichomonas vaginalis and certain Gram positive and Gram negative microorganisms.

**Pharmacological Properties:**

Clotrimazole is a broad spectrum antimycotic with fungicidal properties. It is active against yeasts and vaginal candidiasis, vaginal trichomoniasis, mixed vaginal infections, bacterial vaginitis and infective leucorrhoea.

**Contraindication:** Possible hypersensitivity to Clotrimazole.

**Indications:**

Vaginal candidiasis, vaginal Trichomoniasis, mixed vaginal infections, bacterial vaginitis and effective leucorrhoea.

**Application and dosage:**

One Clovigal vaginal tablet should be inserted daily, preferably on retiring to bed at night for 6 consecutive nights. It is to be inserted as deeply as possible into the vagina. This is best achieved with the applicator when lying on the back with legs pulled in a little towards the body (see special directions).

The treatment should not be carried out during menstruation but should be completed before this begins.

For complete relief, it is advisable to apply cream to the area around the vagina. For the prevention of reinfection, the partner should be treated locally with cream. Vagina Tablets are colourless and do not stain the underwear.

**Side effects:**

Local reactions including irritating and burning may occur, contact allergic dermatitis has been reported. In cases of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur.

**Pregnancy and Lactation:**

If you are pregnant or think you may be pregnant or nursing, do not use this medication except on the advice of a medical practitioner.

**Warning and Precautions:**

- (1) Not for oral use
- (2) Uses only if you have already had a vagina yeast infection diagnosed by a medical practitioner and you have the same symptom now, otherwise consult your doctor. These symptoms include itching and burning of the vagina sometimes a white discharge.
- (3) Do not use in girls under 12 years of age, except on the advice of a medical practitioner.

Clovigal (clotrimazole vaginal tablet B.P 100mg) should not be administered to pregnant women during the first trimester, since the safety in this regard has not been established. During pregnancy, Clovigal (clotrimazole vaginal tablets B.P 100mg) should be inserted without using an applicator.

**Tolerance**

There is virtually no absorption of the active ingredient through the vaginal mucosa. No systemic effects are therefore to be expected. Vaginal tablets are well tolerated locally.

**Presentation:**

Pack containing 6 Clovigal vaginal tablets, each sealed in aluminium foil, and an applicator. Prior to application, cut out from the aluminium foil one tablet.

**Renal impairment:** See under 'warnings'

A small amount of ointment should be applied to cover the affected area. The area treated may be covered with a gauze dressing.

Any product remaining at the end of treatment should be discarded.

Do not mix with other preparations as there is a risk of dilution, resulting in a reduction in the antibacterial activity and potential loss of stability of the Mupirocin in the ointment.

However, stability and antibacterial activity of Mupirocin in pre-mixed ready to use combination formulation is not affected. Patients not showing a clinical response within 7 days should be re-evaluated.

**Contraindications:** Mupirocin ointment should not be used on patients with a history of hypersensitivity to any of its constituents.

**Special Warnings and Special Precautions for Use:**

Patients with renal impairment, elderly patients: No restrictions unless to the condition being treated could lead to absorption of polyethylene glycol and there is evidence of moderate or severe renal impairment.

This Mupirocin ointment is not suitable for:

- Ophthalmic use
- Intranasal use (in neonates or infants). Use in conjunction with cannulae
- At the site of central venous cannulation

For intranasal use, a separate presentation, mupirocin nasal is available.

Avoid contact with eyes. If contaminated, the eyes should be thoroughly irrigated with water until the ointment residues have been removed. Polyethylene glycol can be absorbed from open wounds and damaged skin and is extracted by the kidneys. In common with other polyethylene glycol based ointments, mupirocin ointment should not be used in conditions where absorption of large quantities of polyethylene glycol is possible, especially if there is evidence of moderate or severe renal impairment. In the rare event of a possible sensitization reaction or severe local irritation occurring with the use of mupirocin ointment treatment should be discontinued, the product should be rinsed off and appropriate alternative therapy for the infection instituted.

As with other antibacterial products, prolonged use may result in over-growth of non-susceptible organisms.

**INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION.**

No drug interaction have been reported.

**USE IN PREGNANCY AND LACTATION**

Adequate human data on use during pregnancy are not available. However animal studies have not identified any risk to pregnancy or embryo-foetal development.

Adequate human and animal data on use during lactation are not available. If cracked nipple is to be treated, it should be thoroughly washed, prior breastfeeding.

## UNDESIRABLE EFFECTS

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common ( $\geq 1/10$ ), common, ( $\geq 1/100, < 1/10$ ), uncommon ( $\geq 1/100, < 1/100$ ) rare ( $\geq 1/10,000, < 1/1000$ ), very rare ( $\geq 1/10,000$ ), including isolated reports. Common and uncommon adverse reactions were determined from pooled safety data from a clinical data population of 1573 treated patients encompassing 12 clinical studies. Very rare adverse reactions were primarily determined from post-marketing experience data and therefore refer to reporting rate rather than the true frequency.

### **Immune system disorders**

Very rare: systemic allergic reaction have been reported with Mupirocin ointment

Skin and subcutaneous tissue disorders:

Common: Burning localized to the area of application

Uncommon: itching, erythema, stinging and dryness localized to the area of application

Uncommon: Cutaneous sensitization reactions to mupirocin or the ointment base.

PHARMACOKINETIC PROPERTIES: Absorption

Mupirocin is poorly absorbed through intact human skin. However, if it is absorbed (e.g. through broken/diseased skin) or it is given systemically, it is metabolized to the microbiologically inactive metabolite monic acid and rapid excreted.

Excretion: mupirocin is rapidly eliminated from the body by metabolism to its inactive metabolite monic acid which is excreted mainly by the kidney (90%)