

1. Name of the medicinal product

Vaginal Cream 2% w/w

2. Qualitative and quantitative composition

Clotrimazole 2% w/w.

Excipients with known effect:

Cetostearyl alcohol 100mg in each gram of cream

Benzyl alcohol 20mg in each gram of cream

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

White smooth, homogeneous cream. Free from gritty particles

4. Clinical particulars

4.1 Therapeutic indications

Transporin C Cream is recommended for the treatment of candidal vulvitis. It should be used as an adjunct to treatment of candidal vaginitis.

It can also be used for treatment of the sexual partner's penis to prevent re-infection.

4.2 Posology and method of administration

Vaginal Cream should be applied to the vulva and surrounding area. It can also be applied to the sexual partner's penis to prevent re-infection.

Adults

The cream should be applied thinly two or three times daily and rubbed in gently.

Treatment should be continued until symptoms of the infection disappear. However, if after concomitant treatment of the vaginitis, the symptoms do not improve within seven days, the patient should consult a doctor.

If the cream is being used for treatment of the sexual partner's penis it should be applied two or three times daily for up to two weeks.

Children

There is no clinical experience in the use of Transporin C Cream in children.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Medical advice should be sought if this is the first time the patient has experienced symptoms of candidal vaginitis.

Before using Transporin C Cream medical advice must be sought if any of the following are applicable:

- more than two infections of candidal vaginitis in the last six months
- previous history of a sexually transmitted disease or exposure to partner with sexually transmitted disease
- pregnancy or suspected pregnancy

- aged under 16 or over 60 years
- known hypersensitivity to imidazoles or other vaginal antifungal products

Transporin C Cream should not be used if the patient has any of the following symptoms whereupon medical advice should be sought:

- irregular vaginal bleeding
- abnormal vaginal bleeding or a blood-stained discharge
- vulval or vaginal ulcers, blisters or sores
- lower abdominal pain or dysuria
- any adverse events such as redness, irritation or swelling associated with the treatment
- fever or chills
- nausea or vomiting
- diarrhoea
- foul smelling vaginal discharge

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g., contact dermatitis). The product also contains benzyl alcohol which may cause allergic reactions and mild local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently, the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.6 Fertility, pregnancy and lactation

Pregnancy:

There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses (see section 5.3). At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted.

Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife

Lactation:

There are no data on the excretion of clotrimazole into human milk. However, systemic absorption is minimal after administration and is unlikely to lead to systemic effects. Clotrimazole may be used during breastfeeding.

Fertility:

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

4.7 Effects on ability to drive and use machines

Clotrimazole cream has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

Frequency not known. As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible/

Immune system disorder: anaphylactic reaction, angioedema, hypersensitivity

Vascular disorder: syncope, hypotension

Respiratory, thoracic and mediastinal disorders: dyspnea

Skin and subcutaneous tissue disorders: blister, dermatitis contact, erythema, paraesthesia, skin exfoliation, pruritus, rash, urticaria, stinging skin/burning sensation skin.

General disorders and administration site conditions: application site irritation, application site reaction, oedema, pain.

Reporting of suspected adverse reactions

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Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows

continued monitoring of the benefit/risk balance of the medicinal product. Health care providers are asked to

report any suspected adverse reactions to the marketing authorisation holder, or, if available, via the national reporting system (see details below).

Paper based reporting: TMDA yellow card

Online reporting: <https://sqr.tmda.go.tz/>

*USSD reporting: send a simple short text message to report any suspected Adverse Drug Reaction by dialing *152*00# and follow the instructions*

4.9 Overdose

No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote. However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives

ATC Code: D01A C01

Mechanism of Action

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeasts, moulds, etc.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. *In vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerella vaginalis), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococci - in concentrations of 0.5-10 µg/ml substrate.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

5.2 Pharmacokinetic properties

Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. Pharmaceutical particulars

6.1 List of excipients

Polysorbate 60 BP (Sorbitan monostearate)
Cetyl Palmitate
Cetostearyl Alcohol
Benzyl Alcohol
Isopropyl Myristate
Chlorocresol
Cetomacrogol 1000
Simethicone Emulsion 30%
Disodium Hydrogen Phosphate Dodecahydrate

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30C. Keep in dry place, protect from light

6.5 Nature and contents of container

Translipo C Vaginal Cream is packed in 15gm Aluminum Collapsible tube packed in printed carton along with insert and applicator.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

Centaur Pharmaceuticals Pvt. Ltd,
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8. Marketing authorisation number(s)

TAN 20 HM 0105

9. Date of first authorisation/renewal of the authorisation

July 09, 2020

10. Date of revision of the text

October 11, 2023