SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Candigo 10% Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains: Clotrimazole BP…… 100 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White, smooth, viscous, uniform cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Clotrimazole is recommended for the treatment of candidal vaginitis and mixed vaginal infections where *Trichomonas* is present or suspected. This product is not recommended as sole treatment for pure *Trichomoniasis* except in cases where systemic therapy is contra-indicated.

Clotrimazole is recommended for the treatment of candidal vaginitis.

4.2 Posology and method of administration

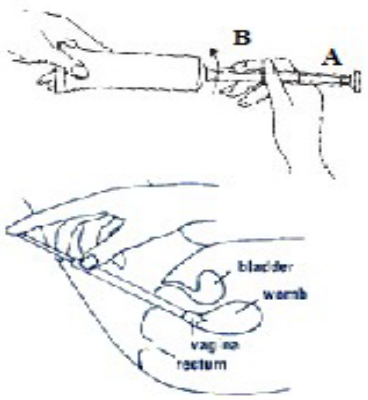
The cream should be administered intravaginally using the applicator supplied.

Adults:

The contents of the filled applicator (7g) should be inserted as deeply as possible into the vagina, preferably at night. A second treatment may be carried out if necessary.

Method of administration

1. Pull out plunger A until it stops. Place cream into the applicator.
2. Insert applicator containing the cream carefully as deeply as is comfortable into the vagina. (This is best done with the patient lying on her back with the knees bent up.)
3. Push plunger A until it stops, thereby administering the cream into the vagina. Remove the applicator.



4.3 Contraindications

Hypersensitivity to clotrimazole or any other ingredient in this medicine Hypersensitivity to cetostearyl alcohol.

4.4 Special Warnings and Precautions For Use

Treatment during the menstrual period should not be performed due to the risk of the cream being

washed out by the menstrual flow. The treatment should be finished before the onset of menstruation.

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product.

Vaginal intercourse should be avoided in case of vaginal infection and while using this product because the partner could become infected.

Children: Not for use in children under 16.

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.

Simultaneous treatment with vaginal clotrimazole and oral tacrolimus (FK- 506; immunosuppressant) can lead to increased levels of tacrolimus in the plasma.

Clotrimazole may reduce the effect of other topical antifungal agents, especially polyene antibiotics (nystatin, natamycin, amphotericin B). At high concentrations of dexamethasone reduces the antifungal activity of clotrimazole. Propyl ester of p- hydroxybenzoic acid in high concentrations, enhances the antifungal effect of clotrimazole.

4.6 Pregnancy and Lactation

Data on a large number of exposed pregnancies indicate no adverse effects of Clotrimazole on pregnancy or on the health of the foetus/newborn child. To date, no relevant epidemiological data are available.

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

During pregnancy the treatment should be carried out with clotrimazole pessary, since these can be inserted without using an applicatory.

4.7 Effects on Ability to Drive and Use Machines

None applicable

4.8 Undesirable Effects

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

Immune system disorders:
Allergic reaction (syncope, hypotension, dyspnea, urticaria, pruritus)

Reproductive system and breast disorders:
Genital peeling, pruritus, rash, oedema, discomfort, burning, irritation, pelvic pain

Gastrointestinal disorders:
Abdominal pain

Reporting of suspected adverse reactions
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. Healthcare professionals are asked

to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

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). It should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gynecological anti-infectives and antiseptics. Imidazole derivatives. Clotrimazole. **ATC code:** G01AF02.

5.1 Pharmacodynamic properties

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

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.
Antifungal agent from the group of imidazole derivatives for topical and local (intravaginal) application, reduces the synthesis of ergosterol, which is part of the microbial cell membrane wall, and causes a change in its structure and properties. In low concentrations acts fungistatically and in large concentrations - fungicide, not only in proliferating cells. The fungicidal concentrations interacts with mitochondrial and peroxidase enzymes, thereby increasing the concentration of hydrogen peroxide to toxic levels, which also contributes to the destruction of fungal cells. It is active against pathogenic dermatophytes (Trichophytonrubrum, Trichophytonmentagrophytes, Epidermophytonfloccosum, Microsporumcanis), yeasts and fungi (the genus Candida, Torulopsisglabrata, the genus Rhodotorula, Malassezia furfur), agents of multi-colored lichen, erythrasma, Gram-positive (Staphylococcus, Streptococcus, Corynebacteriumminutissimum) and Gram-negative bacteria (Bacteroides, Gardnerellavaginalis), Trichomonasvaginalis.

5.2 Pharmacokinetic properties

Pharmacokinetic investigations after vaginal application have shown that only a small amount of clotrimazole (3 – 10% of the dose) is absorbed. Due to the rapid hepatic metabolism of absorbed clotrimazole into pharmacologically inactive metabolites the resulting peak plasma concentrations of clotrimazole after vaginal application of a 500mg dose were less than 10 ng/ml, reflecting that clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to the information included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tefose-63, Light Liquid Paraffin, Cetostearyl Alcohol, Benzyl Alcohol, Butylated Hydroxy Toluene (BHT), Polysorbate-60, Sodium Phosphate Monobasic Dihydrate, Triethanolamine, Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in a cool place below temperature 30°C. Keep out of reach and sight of children.

6.5 Nature and contents of container

7 g of Candigo cream in the aluminium tube.
Each tube is packed in carton with an applicator and packaging insert for medical use.

6.6 Special precautions for disposal and other handling

Nothing specific.

7. MARKETING AUTHORISATION HOLDER

Kusum Healthcare Pvt. Ltd.
SP-289(A), RIICO Industrial Area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan) India

8. MARKETING AUTHORISATION NUMBER(S)

04555/07019/NMR/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 July 2019

10. DATE OF REVISION OF THE TEXT

08/2023

11. REFERENCE

SmPC published on electronic medicines compendium
https://www.medicines.org.uk/emc#gref

The MHRA published product information
https://products.mhra.gov.uk/