SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENERIC: Clotrimazole Vaginal Cream USP 2%w/w

BRAND NAME: CANIMAKS-V2

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole USP…….. 2% w/w

Benzyl Alcohol (As Preservative) …… 1% w/w

In a Cream Base …….. q.s.

3. PHARMACEUTICAL FORM:

Semi Solid Dosage Form – Cream.

White soft homogenous cream.

4.CLINICAL PARTICULARS

4.1 Therapeutic Indication:

For the relief of vaginal itching, burning and discharge associated with recurrent vaginal yeast infections (vaginal candidiasis).

4.2 Posology and method of administration:

Dosage:

One applicator full of CANI-MAKS V2 (about 5 gm) should be inserted deeply in the vagina every night on retiring for six consecutive days. If individual cases should require it, two applications, can be used daily, i.e. one in the morning and one in the evening, for six to twelve days. Use even during menstruat1on, although it is recommended that the treatment should not be carried out during menstruation but should be completed before this begins.

For Candida vulvitis or Vulvo vaginitis the vaginal cream should be applied thinly to the external genitalia two or three times a day for one to two weeks.

For the prevention of re-infection the partner should be treated locally at the same time.

Direction for use of the applicator

1.Remove the cap from the tube & attach the applicator to the mouth of the tube.

2.Squeeze the tube from the bottom to fill the cream (about 5 gm) into the cylinder and push the plunger till the cylinder is filled.

3.Remove the filled applicator from the tube and close the tube with the cap.

4.Gently insert the applicator into the vagina as deep as possible. Press the plunger to empty the content of the applicator completely.
This is best achieved when lying on the back with legs pulled little towards the body.

5.Remove the applicator from vagina.

6.Clean the applicator after each use.
Separate plunger and cylinder by pulling out plunger with slight force.
Wash with soap and lukewarm water. Rinse thoroughly. Reassemble the applicator by inserting plunger into cylinder.

4.3 Contraindications:

Possible allergy to clotrimazole or any other imidazole agents. The possibility of absorption of clotrimazole when administered vaginally cannot be excluded. Safety in pregnancy has not been established.

4.4 Warning and precautions for use

Use only if you have already had a vaginal yeast infection diagnosed by a medical practitioner and you have the same symptoms now, otherwise consult your doctor. These symptoms include itching and burning of the vagina and sometimes a white discharge, if there is no improvement in three days or if symptoms have not disappeared within seven days, then consult medical practitioner as not all vaginal infections are caused by yeasts.

Consult medical practitioner if you have abdominal pain, fever or a foul – smelling vaginal discharge before or during the use of this medication.

If symptoms recur within two months, consult a medical practitioner.

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

Do not use in girls under twelve years of age, except on the advice of a medical practitioner.

If skin rash or new irritation occurs, discontinue use.

4.5 Drug Interactions

Concomitant medication with vaginal Clotrimazole and oral tacrolimus (FK-506; immunosuppressant) might lead to increased tacrolimus plasma levels. Patients should thus be closely monitored for signs and symptoms of tacrolimus Overdosage, if necessary by determination of the respective plasma levels.

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 & Lactation

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.

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.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:

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/ metabolites in milk after intravenous administration. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

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 Adverse Effects

Skin and subcutaneous tissue disorders: blisters, discomfort/pain, oedema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning.

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:

5.1 Pharmacodynamic properties:

ATC Code: G01A F02 Gynaecological antiinfectives and antiseptics – imidazole derivatives

Clotrimazole is an imidazole derivative with a broad spectrum of antimycotic activity.

Mechanism of Action

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

Pharmacodynamic Effects

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 μg/ml substrate. 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.

In addition to its antimycotic action, clotrimazole also acts on Trichomonas vaginalis, gram-positive microorganisms (Streptococci/Staphylococci) and gram-negative microorganisms (Bacteroides/Gardnerella vaginalis). It has no effect on lactobacilli.

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 and exerts a trichomonacidal action at 100 μg/ml.

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 vaginal application have shown that only a small amount of clotrimazole (3 – 10%) 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.

Pharmacokinetic investigations after dermal application have shown that clotrimazole is practically not 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 μg/ml, reflecting that clotrimazole applied topically does not lead to measurable systemic effects or side effects.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol, White Soft Paraffin, Cetomacrogol 1000, Cetostearyl alcohol, Dimethisone, Liquid Paraffin (Heavy), Propylene Glycol, Purified Water, Disodium EDTA, Glyceryl Monostearate.

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months

6.4 Special precautions for storage:

Do not store above 30°C. Protect from light.

Keep the medicine out of reach of children.

6.5 Nature and contents of container

20g cream in a collapsible aluminium tube along with Plastic Applicator with plunger.

7. APPLICANT
Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,
Vapi - 396 195. Gujarat, INDIA.

8. NATIONAL REGISTRATION NUMBER

07264/09516/NMR/2022

9. DATE OF AUTHORISATION

11/04/2022

10. DATE OF REVISION OF THE TEXT

04/03/2019