SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Pricostat V Cream 2% w/w

2. Qualitative and quantitative composition

Clotrimazole 2% w/w

Cetostearly Alcohol 4% w/w

Chlorocresol 0.1%

For full excipients, see section 6.1

3. Pharmaceutical form

Vaginal cream.

White, smooth shining cream with characteristic aroma.

4. Clinical particulars

4.1 Therapeutic indications

Pricostat V Cream 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 (5g) should be inserted as deeply as possible into the vagina, preferably at night. A second treatment may be carried out if necessary.

Generally:

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.

4.3 Contraindications

Hypersensitivity to Clotrimazole or any other excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Patients should be advised to consult their physician if the symptoms have not been relieved within one week of using Pricostat V Cream. Pricostat V Cream can be used again if the candidal infection returns after 7 days. However, if the candidal infection recurs more than twice within six months, patients should be advised to consult their physician.

This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

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.

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

4.6 Fertility, pregnancy and 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 are 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 vaginal 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.

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

Lactation:

Available Pharmacodynamic/toxicological data in animals have shown excretion of Clotrimazole/metabolites in milk after intravenous administration (see section 5.3). 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
The medication has no or negligible influence on the ability to drive or use machinery.

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, edema, erythema, discomfort, burning, irritation, pelvic pain, vaginal haemorrhage.

Gastrointestinal disorders: abdominal pain.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 the Yellow Card Scheme.

4.9 Overdose
No risk of acute intoxication is seen as it is unlikely to occur following a single vaginal or dermal application of an overdose (application over a large area under conditions favorable 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: Gynecological anti-infective and antiseptics – imidazole derivatives

ATC Code: G01A F02

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 fungi static 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.

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
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
Light Liquid Paraffin, Cetomacrogol 1000, Cetostearyl Alcohol, Micro wax, Propylene Glycol, Chlorocresol, Glycerine Monostearate, Light White oil & Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months.

6.4 Special precautions for storage

Do not store above 30°C, protect from light.

6.5 Nature and contents of container
Internally lacquered aluminium, blind end tubes containing 15gm of product, closed with a polyolefin cap in a cardboard outer with an applicator of pack size 5g.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorization holder

PRINCE PHARMACEUTICALS CO. LTD,
PLOT NO. 4/1, BUHONGWA INDUSTRIAL AREA,
P.O.BOX 11415,
MWANZA, TANZANIA.

8. Marketing authorization number(s)

TAN 22 HM 0414

9. Date of first authorization/renewal of the authorization

21/09/2022

10. Date of revision of the text

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