SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CANISON (Clotrimazole Cream USP 1%w/w)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole USP... 1 % w/w

Cream base..... q.s.

3. PHARMACEUTICAL FORM

Cream

Excipients with known effect: cetostearyl alcohol 72mg in each gram of cream, benzyl alcohol 10mg in each gram of cream.

For a full list of excipients, see section 6.1

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

For the treatment of:

i. All dermatomycoses due to moulds and other fungi (e.g. Trichophyton species)

ii. All dermatomycoses due to yeasts (Candida species). These include ringworm (tinea) infections (e.g. athlete's foot), paronychia, pityriasis versicolor, erythrasma and intertrigo.

iii. Skin diseases showing secondary infection with these fungi.

iv. Candidal nappy rash, vulvitis and balanitis.

4.2 Posology & Method of Administration:

Posology

There is no separate dosage schedule for the young or elderly. Method of administration

The cream should be applied thinly and evenly to the affected area 2-3 times daily and rubbed in gently. A strip of cream (½ cm long) is enough to treat an area of aboutthe size of the hand.

If the feet are infected, they should be thoroughly washed and dried, especially between the toes, before applying the cream.

Treatment should be continued for at least one month for dermatophyte infections, or for at least two weeks for candidal infections.

4.3 Contraindications:

Hypersensitivity to the active substance orto any of the excipients . Do not use the cream to treat nail or scalp infections.

4.4 Special Warnings and Precautions for Use: Warning & Precautions

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

Instruct patients not to smoke or go near naked flames- risk of severe bums. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Information for Patients

The patient should be advised to:

1. Use the medication for the full treatment time even though the symptoms may have improved. Notify the physician if there is no improvement after four weeks of treatment.
2. Inform the physician if the area of application shows signs of increased irritation (redness, itching, burning, blistering, swelling, oozing) indicative of possible sensitization.
3. Avoid the use of occlusive wrappings or dressings.
4. Avoid sources of infection or reinfection.

Laboratory Tests

If there is lack of response to Clotrimazole Cream, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens before instituting another course of antimycotic therapy.

CAUTION:

FOR EXTERNAL USE

ONLY. NOT FOR

OPHTHALMIC USE.

Keep this and all medication out of the reach of children.

4.5 Drug 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 Pregnancy, Lactation & Fertility:

Pregnancy:

There is a limited amount of data from the use of clotrimazole in pregnant women. 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 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.

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:

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

Immune system disorders: anaphylactic reaction, angioedema, hypersensitivity. Vascular disorders: syncope, hypotension.

Respiratory, thoracic and mediastinal disorders: dyspnoea.

Skin and subcutaneous tissue disorders: blisters, dermatitis contact, erythema, parasthesia, 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
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 pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) **https://pv.pharmacyboardkenya.org/**

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

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the 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 offungi 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 theexception of Enterococci - in concentrations of0.5-10 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 Nonclinical properties

Animal Toxicology

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Cetomacrogol 1000, Light Liquid Paraffin, White Soft Paraffin, Cetostearyl Alcohol, Propylene Glycol, Chlorocresol, Benzyl Alcohol,

Disodium
Edetate,
Disodium Hydrogen Phosphate Dihydrate (Sodium Phosphate Dihydrate), Sodium Dihydrogen Phosphate Dihydrate (Sodium Acid Phosphate), Purified Water.

6.2 Incompatibilities

None

6.3 Shelf Life

36 Months

6.4 Special Precautions for Storage:

Store below 30°C and Protect from Light.

6.5 Nature and Contents of Container

An Aluminium tube containing 15 g/20 g cream is packed in a carton along with Pack Insert. A Laminated tube containing 15 g/20 g cream is packed in a carton along with Pack Insert.

6.6 Instructions for use and handling <and disposal>

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Agio Pharmaceuticals Ltd.,
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Estate, Andheri-Kurla
Road, Safedpool, Andheri
East, Mumbai City,
Maharashtra - 400 072.
India.

8. Marketing Authorisation Number(s)

H2006/569

9. Date of First Authorisation/Renewal of the Authorization

2006

10. Date of Revision of the Text

26/07/2026