SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

URIEZORAL (Ketoconazole Cream 2 % w/w)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

3. PHARMACEUTICAL FORM

Topical Cream

Sr. No.	Ingredients	Specification	Label claim (In % w/w)	Overages (in %)	Each 20 gm contains (in mg)	Reason for inclusion

1.	Ketoconazole	BP	2 %	8	648.00	Medicament
2.	Cetyl Alcohol	BP	-	-	600.00	Emulsifier
3.	Polysorbate 80 (Tween 80)	BP	-	-	30.00	Emulsifying agent
4.	Propylene Glycol	BP	-	-	6000.00	Solvent
5.	Isopropyl Myristate	BP	-	-	300.00	Solvent
6.	Stearyl Alcohol	BP	-	-	2250.00	Emulsifier
7.	Sorbitan Mon stearate (Span-60)	BP	-	-	600.00	Emulsifying agent
8.	Polysorbate 60 (Tween-60)	BP	-	-	450.00	Emulsifying agent
9.	Sodium Sulphite	BP	-	-	60.00	Antioxidant
10.	Purified Water	BP	-	-	19110	Aq. base

4. Clinical particulars

4.1 Therapeutic indications

Ketoconazole Cream contains a medicine called ketoconazole. This belongs to a group of medicines called 'antifungals'. This Cream is used for fungal and yeast infections of the skin in adults.
Infections may appear on the:

- Trunk, chest or back
- Hands or feet
- Scalp or face
- Groin or genitals

Ketoconazole Cream works by killing the fungus that causes the infection.

4.2 Dosage and method of administration

Cutaneous candidiasis, tinea corporis, tinea cruris, tinea pedis and tinea (pityriasis) versicolor: It is recommended that Ketoconazole Cream 2% be applied once daily to cover the affected and immediate surrounding area. Clinical improvement may be seen fairly soon after treatment is begun; however, candidal infections and tinea cruris and corporis should be treated for two weeks in order to reduce the possibility of recurrence. Patients with tinea versicolor usually require two weeks of treatment. Patients with tinea pedis require six weeks of treatment. Seborrheic dermatitis: Ketoconazole Cream 2% should be applied to the affected area twice daily for four weeks or until clinical clearing.
If a patient shows no clinical improvement after the treatment period, the diagnosis should be redetermined.

4.3 Contraindications

URIEZORAL (Ketoconazole Cream 2%) is contraindicated in persons who have shown hypersensitivity to the active or excipient ingredients of this formulation.

4.5 Special warnings and precautions for use

Ketoconazole cream is not for ophthalmic use.

URIEZORAL (Ketoconazole Cream 2%) contains sodium sulfite anhydrous, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non- asthmatic people.

Talk to your doctor or pharmacist before using this medicine:

• If you have recently used a cream, ointment or lotion on your skin infection that contains a steroid:

• You should continue to apply a mild steroid (such as hydrocortisone) cream, ointment or lotion in the morning whilst applying Ketoconazole Cream in the evening. The mild steroid treatment can then be gradually stopped over a period of 2-3 weeks.

If you have any questions about stopping your steroid cream, ointment or lotion, ask your doctor or pharmacist.

Children and adolescents:

Ketoconazole Cream is not recommended for use in children under 18 years of age. Other

medicines and Ketoconazole Cream

Ketoconazole Cream does not normally react with other medicines. However, tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

Pregnancy and breast-feeding:

Ketoconazole Cream can be used if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Personal hygiene:

•Unless the affected skin is on your hands, wash your hands with soap and water after using the cream

•Washing your hands after using the cream will stop you spreading the infection to other parts of your body or to other people

•Do not allow other people to use your flannel or towel. This will stop them from getting your infection

• Clothing that touches infected skin should be washed and changed often.

5. Interaction with other medicinal products and other forms of interaction

Not Applicable.

5.1 Undesirable effects

Side Effects includes:

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Ketoconazole Cream and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

• Severe irritation or reddening of the skin where the cream has been used or other signs of allergy during the first few days of treatment.

This can affect fewer than 1 in 10 people

• Peeling or blistering of the skin. This can affect fewer than 1 in 100 people

Tell your doctor or pharmacist if you notice or suspect any of the following side effects:

Common side effects (affects fewer than 1 in 10 people)

• Burning sensation

Uncommon side effects (affects fewer than 1 in 100 people)

• Problems where the cream has been used such as:

- Bleeding
- Discomfort
- Dryness
- Inflammation (contact dermatitis)
- Tingling

• Rash, hives (also known as nettle rash or urticaria)

• Sticky skin

5.3 Overdose

Not Applicable

6. PHARMACOLOGICAL PROPERTIES

a. Pharmacodynamics properties

In studies of the mechanism of action in fungal cultures, the minimum fungicidal concentration of Ketoconazole caused leakage of intracellular phosphorous compounds into the ambient medium with

concomitant breakdown of cellular nucleic acids, and accelerated potassium efflux. Both of these events began rapidly and extensively after addition of the drug to the cultures.

b. Pharmacokinetic properties

The absorbance of ketoconazole from the gastrointestinal tract is variable and increases with decreasing stomach pH. It is recommended that ketoconazole is given with food to increase absorption and reduce gastrointestinal disturbances, although reduced rate and extent of absorption have occurred when given after a meal. Mean peak plasma concentration of about 3.5 µg per ml have been obtained 2 hours after administration of 200 mg by mouth. After systemic application, ketoconazole is not systematically absorbed and does not produce detectable plasma concentrations. Ketoconazole is more than 90 % bound to plasma proteins, mainly albumin. It is widely distributed and appears in breast milk. Penetration into the CSF is poor. The elimination of ketoconazole is reported to be biphasic, with an initial half-life of 2 hours and a terminal half-life of about 8 hours.

Ketoconazole is metabolized in the liver to inactive metabolites. It is excreted as metabolites and unchanged drug chiefly in the faces; some is excreted in the urine.

c. Preclinical safety data

Not Applicable.

7. PHARMACEUTICAL PARTICULARS

a. Incompatibilities

None known

b. Shelf life

36 Months

c. Special precautions for storage

Store in cool, dry and dark place.

FOR EXTERNAL USE ONLY

d. Nature and contents of container

1 x 20g Tube

e. Special precautions for disposal <and other handling>

No special requirements.

8. <APPLICANT/MANUFACTURER>

LESANTO LABORATORIES

Plot No. 9, 10, 11 & 20,

Survey No. 53,

Palghar (E) - 401 404, India