

# Summary of Product Characteristics

## KANDIMAX 1% (Clotrimazole Dusting Powder)

### 1. Name of the medicinal product

KANDIMAX 1% (Clotrimazole Dusting Powder)

### 2. Qualitative and quantitative composition

Clotrimazole USP            1% w/w

Zinc Oxide BP            1.75% w/w

Talc BP                            q.s.

For the full list of excipients, see section 6.1

### 3. Pharmaceutical form

Dusting Powder

### 4. Clinical particulars

#### 4.1 Therapeutic indications

KANDIMAX 1% Powder is ideal for prevention or treatment of fungal infections such as ringworms, dhotie itch (fungal infection on the skin of the groin region), athlete's foot and infections resulting from excessive sweating.

#### 4.2 Posology and method of administration

KANDIMAX 1% Powder should be sprinkled onto the affected areas 2-3 times a day for a period of two weeks to speed up the process of healing and see faster results. The powder may also be dusted inside articles of clothing and footwear which are in contact with the infected area.

#### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Do not use the powder to treat nail or scalp infections. Consult your doctor immediately in case your situations don't get better even after using KANDIMAX 1% Powder.

#### 4.4 Special warnings and precautions for use

- Always consult with your physician before starting a Clotrimazole treatment, especially for treating infections in your intimate parts.
- Do not use KANDIMAX 1% Powder if your doctor confirms a potential drug interaction.
- It is a topical treatment. So, make sure that it does not enter your body under any circumstance.
- If you are hypersensitive to imidazole, using latex contraceptives, going through the first trimester of pregnancy, or even a lactating mother, stay away from using this absorbent powder.
- Do not use Clotrimazol and zinc oxide topical powder on deep skin wounds or severe burns.
- Consult the physician if symptoms persist for more than 7 days.
- Keep out of the reach and sight of children.

#### 4.5 Interaction with other medicinal products and other forms of interaction

All drugs interact differently for person to person. You should check all the possible interactions with your doctor before starting any medicine. Do let your doctor know if you smoke, consume alcohol or caffeinated drinks, or use illegal drugs as these may interfere with the action of your medication. Make sure to inform your doctor of any medical conditions you may have, or any family history of medical problems. Do not start or stop using any medicine without consulting.

#### 4.6. Fertility, pregnancy and lactation

##### Pregnancy

Data on a large number of exposed pregnancies indicate no adverse effects of KANDIMAX 1% Powder on pregnancy or on the health of the foetus / newborn child. To date, no relevant epidemiological data are available.

The topical forms of this medicine are relatively safe for use until the first trimester of pregnancy. However, they should be used only if clearly needed and only under the supervision of your doctor.

## Breast-feeding

Though the effects are not ascertained, it is recommended to consult your doctor before taking the medicine.

### 4.7 Effects on ability to drive and use machines

In clinical trials that assessed driving ability, no impairment occurred in patients using the Clotrimazole dusting powder.

### 4.8 Undesirable effects

Use of too much Clotrimazole Dusting Powder might cause mild to serious side effects. These include flaking or peeling of the skin, hypersensitivity, tenderness, redness, erythema, irritation, formation of small bumps, swelling, blister, stinging or burning sensation, contact dermatitis, gastrointestinal disorders, dysuria, and depression. If any of these persist, consult your physician immediately.

Rarely patients may experience local mild burning or irritation immediately after applying the powder. Very rarely the patient may find this irritation intolerable and stop treatment.

Other undesirable effects :

Body as a whole:	allergic reaction, pain
Skin and appendages:	pruritis, rash

### 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

Pharmacotherapeutic group: Antifungal and Antibacterial

Clotrimazole, an imidazole derivative with a broad spectrum of antimycotic activity, inhibits biosynthesis of the sterol ergosterol, an important component of fungal cell membranes. Its

action leads increased membrane permeability and apparent disruption of enzyme systems bound to the membrane. Clotrimazole are used together to treat cutaneous tinea infections. In studies in fungal cultures, the minimum fungicidal concentration of clotrimazole 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. The primary action of clotrimazole is against dividing and growing organisms.

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.

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.

Zinc oxide is mildly astringent and is used topically as a soothing and protective application in eczema and slight excoriations. Zinc oxide reflects ultra violet radiation and is used in sunscreens. Zinc oxide is mildly astringent, soothing and protective.

## 5.2 Pharmacokinetic properties

Clotrimazole :

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.

Absorption : Poorly and erratically absorbed orally and minimal topical absorption.

Protein Binding : 90%

Excretion : Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug.

Metabolism : Hepatic (metabolized to inactive metabolites)

Zinc Oxide :

It is unlikely that any Zinc Oxide is absorbed through the skin. Zinc salts are poorly absorbed from the gastro-intestinal tract. Only a small proportion of dietary zinc is absorbed. Zinc is widely distributed throughout the body and is excreted in the faeces with only traces appearing in the urine.

### 5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

## 6. Pharmaceutical particulars

### 6.1 List of excipients

Starch, Aerosil, Purified Talcum and Perfume English Lavender.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years

### 6.4 Special precautions for storage

Store at a temperature not exceeding 30°C

### 6.5 Nature and contents of container

High-density polyethylene bottle with printed sleeve having inner dusting cap and outer press cap, containing 100 gm of powder.

Also available in 50 gm pack.

#### 6.6 Special precautions for disposal

No special requirements.

#### 7. MARKETING AUTHORISATION HOLDER

Kremoint Pharma Pvt. Ltd.

B-8, Additional Ambernath, MIDC, (East), Thane, Ambernath – 421506

Phone No: +91 251 2620355 / 655 / 273 / 354 / 463

Fax No : + 91 251 2621363 / 364 / 367

E. Mail : [info@kremointpharma.com](mailto:info@kremointpharma.com)