
XKIZORAL CREAM

(Ketoconazole BP 2.00% w/w)

Composition:

- **Ketoconazole BP 2.00% w/w**
  - Ketoconazole is a broad-spectrum antifungal agent that works by inhibiting the growth of fungi by interfering with the fungal cell membrane. It is effective against various fungal and yeast infections, such as **tinea** (ringworm), **pityriasis** (yeast infection causing scaly skin), and **seborrheic dermatitis**.
- **Cream base: q.s.**
  - The cream base is a non-greasy formulation that ensures the active ingredient is evenly distributed and absorbed into the skin.

Indications:

XKIZORAL Cream is indicated for the topical treatment of:

- **Fungal skin infections**: Including conditions like athlete's foot (**tinea pedis**), ringworm (**tinea corporis**), jock itch (**tinea cruris**), and **cutaneous candidiasis**.
- **Seborrheic dermatitis**: A chronic skin condition characterized by scaling and inflammation, especially on the scalp, face, and chest, often caused by the yeast *Malassezia*.
- **Pityriasis versicolor**: A fungal infection causing small, discolored patches of skin, typically on the chest, back, and upper arms.

How XKIZORAL Works:

Ketoconazole, the active ingredient in XKIZORAL Cream, works by blocking the synthesis of ergosterol, an essential component of the fungal cell membrane. This weakens the membrane, causing the contents of the fungal cell to leak out, ultimately killing the fungi and preventing the infection from spreading.

Dosage and Administration:

1. **Preparation**:
    - Wash the affected area with mild soap and water and dry it thoroughly before applying XKIZORAL.
2. **Application**:
    - Apply a thin layer of XKIZORAL Cream to the affected area and a small surrounding area once or twice daily, as directed by your healthcare provider.
    - Rub in gently until fully absorbed.
3. **Duration of Treatment**:
    - For **dermatophyte infections** like ringworm or jock itch, treatment typically lasts for **2 to 4 weeks**.
    - For **seborrheic dermatitis**, it may be used for **2 to 4 weeks**, and as maintenance therapy, the cream can be applied once or twice weekly.
    - **Pityriasis versicolor** usually resolves in **2 to 3 weeks** of treatment.
4. **Important Advice**:
    - Even if symptoms improve, continue the full course of treatment to ensure the infection is completely eradicated and to prevent recurrence.
    - Avoid applying the cream to eyes, mouth, or mucous membranes.

Warnings and Precautions:

- **For external use only**. Do not ingest.
- Avoid contact with the **eyes**, **nose**, **mouth**, or other mucous membranes. In case of accidental contact, rinse thoroughly with water.
- Do not use on **broken or inflamed skin** unless directed by your healthcare provider.
- If irritation or an allergic reaction (such as itching, rash, or swelling) occurs, discontinue use and consult your healthcare provider.
- Avoid prolonged use on **large areas of the body**, as this may increase the risk of side effects.
- Keep XKIZORAL out of the reach of **children**.

Use in Specific Populations:

- **Pregnancy and breastfeeding**: While there is limited absorption through the skin, consult your doctor before using XKIZORAL if you are pregnant or breastfeeding.
- **Pediatric use**: Use in children should be supervised by a healthcare provider.

Possible Side Effects:

While XKIZORAL Cream is generally well-tolerated, some individuals may experience mild side effects. These include:

- **Skin irritation**: Burning, stinging, or redness at the application site.

- **Itching**: Some individuals may experience itching or dryness after application.
- **Allergic reactions**: Rarely, allergic reactions such as rash, swelling, or difficulty breathing may occur. If these symptoms develop, stop using the product and seek medical attention.

If side effects persist or worsen, contact your healthcare provider immediately.

Drug Interactions:

- No significant interactions are expected with XKIZORAL Cream when applied topically. However, it is recommended to inform your doctor of any other medications, creams, or lotions you are using to avoid potential interference.

Contraindications:

XKIZORAL is contraindicated in individuals with:

- **Hypersensitivity** to Ketoconazole or any of the components of the formulation.
- **Pre-existing liver conditions** when taking oral ketoconazole, though this is less of a concern with the topical formulation.

Storage Instructions:

- Store XKIZORAL Cream in a cool, dry place, at a temperature not exceeding **30°C**.
- Protect from direct sunlight and moisture.
- Keep the tube tightly closed after each use.
- **Keep out of the reach of children**.

Packaging:

XKIZORAL Cream is available in a **30g tube** for topical use.

Manufactured by:

Unijules Life Sciences Ltd.
B-35/36, MIDC Industrial Area,
Kalmeshwar - 441501, Nagpur, India.

Marketed by:

Global Young Pharma Limited
Agara Baba Pupa, Road 5,
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