

Patient & Product Information

(Ketoconazole 2% w/w Cream) **Anti-fungal Cream**

Active Ingredients:

Ketoconazole 2.0% w/w

Read this Patient Information carefully before you start using this cream and each time you get a refill. This information does not replace discussing your medical condition or treatment with your healthcare provider.

What is this Cream?

This cream is a topical medication used for:

- Treatment of fungal infections of the skin, such as athlete's foot, ringworm, jock itch, and seborrheic dermatitis (dandruff).
- Treating fungal skin infections caused by various types of fungi, including Candida species.

This Cream is not for:

- Treating skin conditions other than those prescribed by your healthcare provider.
- Use on broken, damaged, or severely irritated skin.

Who can use this Cream?

For Adults and Elderly Patients:

- This cream can be safely used in adults and elderly patients as prescribed by your healthcare provider.

For Children (2 years of age and older):

- Safe for use under adult supervision. Apply only a thin layer to the affected area as directed by your healthcare provider.
- Do not use on large areas of skin or for prolonged periods without consulting a healthcare provider.

For Infants and Toddlers (under 2 years of age):

- Not recommended for use in children under 2 years of age unless directed by a healthcare provider.

Who should not use this Cream?

Do not use this cream if you:

- Are allergic to ketoconazole or any of the ingredients in the cream (see the list of ingredients at the end).
- Have any skin conditions such as open wounds or large-scale burns.
- Are pregnant, especially in the first trimester, unless advised by a healthcare provider.
- Are breastfeeding, unless directed by a healthcare provider.

What should I tell my healthcare provider before using this Cream?

Before using this cream, tell your healthcare provider if you:

- Have any allergies, particularly to ketoconazole or other antifungal medications.
- Have any liver problems or other underlying medical conditions.
- Are pregnant or plan to become pregnant. This cream should only be used in pregnancy if the potential benefit justifies the risk to the fetus.
- Are breastfeeding or plan to breastfeed. The cream may pass into breast milk.
- Tell your healthcare provider about all the medicines you take, including prescription, over-the-counter medicines, vitamins, and herbal supplements.

How should I use this Cream?**For Adults and Children 2 Years and Older:**

- Clean and dry the affected area before applying.
- Apply a thin layer of cream to the affected area 1-2 times daily, or as directed by your healthcare provider.
- Gently rub the cream into the skin until absorbed.
- Continue use for the prescribed duration, even if symptoms improve before completing the treatment.

Children Under 2 Years of Age:

- Use only if prescribed by a healthcare provider. Follow their specific directions.

What are the possible side effects of this Cream?**In Adults and Children 2 Years and Older:****Common side effects:**

- Mild skin irritation or redness at the application site.
- Dryness or peeling of the skin.
- Rare but serious side effects:
 - Severe allergic reactions, such as rash, swelling, or difficulty breathing.
 - Burning or stinging sensation at the application site.

In Infants and Toddlers Under 2 Years of Age:

- Increased risk of skin irritation. Use only under healthcare provider supervision.

How should I store this Cream?

- Store this cream at room temperature, between 20°C to 25°C (68°F to 77°F).
- Keep the tube tightly closed when not in use.
- Keep this cream and all medicines out of the reach of children.

General Information about the safe and effective use of this Cream

- Do not use this cream for a condition for which it was not prescribed.
- Do not share this medication with other people, even if they have the same symptoms.
- You can ask your pharmacist or healthcare provider for information that is written for health professionals.

What are the ingredients in this Medicated Cream?**Active ingredients:**

- Ketoconazole: An antifungal agent that works by inhibiting the growth of fungi on the skin.

Inactive Ingredients:

- Cream base