CREOBIC GOLD CREAM 1% W/W

Terbinafine Hydrochloride (1% w/w)

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What Creobic Gold Cream 1% w/w is used for

Creobic Gold Cream 1% w/w is use for treatment of topical fungal infection caused by dermatophytes; yeast; pityriasis versicolor; and cutaneous candidiasis.

How Creobic Gold Cream 1% w/w works

Creobic Gold Cream 1% w/w contains Terbinafine Hydrochloride. Terbinafine is a fungicidal which destroys the fungus and molds that causes the infection.

Before you use Creobic Gold Cream 1% w/w

- When you must not use it Do not take Creobic Gold Cream 1% w/w if:

- You are allergic or hypersensitive to Terbinafine or to any component of this medication.
- It is not recommended to be used in children.

- Before you start to use it

Tell your doctor if:

- You are pregnant and nursing mother. Pregnant women can only use the medicine if the potential benefits outweigh any potential risks. Terbinafine is found in breast milk. Breastfeeding mother should not use it.
- You are allergic to any medicines.

- Taking other medicines

You should tell your doctor or pharmacist if you are taking any other medicines currently.

It may still be all right for you to take Creobic Gold Cream 1% w/w and your doctor will be able to decide what is suitable for you.

How to use Creobic Gold Cream 1% w/w

- How much to use

Applied once or twice daily by smoothing gently into the affected area

- Athlete's foot, jock itch, tinea ringworm: 1 week of treatment will normally suffice if the cream is applied twice daily.
- Cutaneous candidiasis: 1-2 weeks of treatment.
- Pityriasis (tinea) versicolor: 2
 weeks of treatment. For
 intertriginous infection (where
 two skin areas may touch or rub
 together), the application may be
 covered with gauze strip,
 especially at night.

- When to use it

Your doctor will decide when it is appropriate for you to use Creobic Gold Cream 1% w/w according to the type of condition you have.

- How long to use it

- Apply this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.
- Symptoms usually disappear in a few days. Irregular application or early discontinuation of the treatment increases the risk of relapse. If no sign of healing can be detected after two weeks, you need to see your doctor.

- If you forget to use it

• If you forget to use your cream at a certain time, use it as soon as you remember. However, if it is nearly time for your next application, skip the missed application.

- If you use too much (overdose)

If, by mistake on a few occasions you use more than you should, do not worry. If you apply a lot or a lot is accidentally swallowed, it could make you ill. If accidentally ingest a larger amount of medicine, gastrointestinal disturbances such as nausea, diarrhea and mild abdominal pain is to be expected. Talk to your doctor or go to the hospital as soon as possible.

While you are using it

- Things you must do

- Discuss with your doctor or pharmacist the dos' and don'ts' while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Take the Creobic Gold Cream 1% w/w according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

- Things you must not do

- Do not apply your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single use.

- Things to be careful of

• For external use only. Avoid contact with eyes.

Side effects

Like all medicines, Creobic Gold Cream 1% w/w can cause side effects although not everybody gets them. You are advised to consult doctor/pharmacist for further information. The following side effects have been reported:

 Local irritation such as redness, itching and stinging may occur at the sites of application.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

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Terbinafine Hydrochloride (1% w/w)

Storage and disposal of Creobic Gold Cream 1% w/w

- Storage

Keep Creobic Gold Cream 1% w/w out of reach of children. Store below 30°C. Keep container

well closed and protect from light.

- <u>Disposal</u>

Do not use Creobic Gold Cream 1% w/w after the expiry date which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Creobic Gold Cream 1% w/w is white to off white colored, water miscible cream.

- Ingredients

- Active Ingredient (s): Terbinafine hydrochloride
- Inactive Ingredients:

Cremophor A6, Cremophor A25, Propylene Glycol, Purified Water, Benzyl Alcohol, Liquid Paraffin, Cetostearyl Alcohol, Sodium Dihydrogen Phosphate Anhydrous, Sodium Hydroxide.

- <u>MAL Number</u> MAL08042384X

Manufacturer and product registration holder

Kotra Pharma (M) Sdn Bhd No. 1, 2 & 3, Jalan TTC 12, Cheng Industrial Estate, 75250 Melaka, Malaysia.

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