



Package leaflet: Information for the patient

BADRUF Cream

(Clotrimazole, Betamethasone and Neomycin Cream)

Please read this leaflet carefully before using this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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1. What BADRUF Cream is and what it is used for?

BADRUF Cream is indicated for topical use in the treatment of a wide range of eczemas and other inflammatory and allergic infections of the skin caused by various bacteria/fungi. These conditions include contact dermatitis, follicular dermatitis, impetigo, intertrigo, eczematoid dermatitis, non-specific pruritus etc.

BADRUF Cream is used for Antifungal, Antibacterial & Anti-Inflammatory conditions. It contains Clotrimazole, Betamethasone and Neomycin which are used as;

Clotrimazole is a topical anti-fungal medicine used to treat some fungal infections of the skin.

Betamethasone belongs to a group of medicines called topical corticosteroids which are used on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

Neomycin, an antibiotic, is used to prevent or treat skin infections caused by bacteria. It is not effective against fungal or viral infections.

2. Before you take BADRUF Cream

Do not use BADRUF Cream

- If you are allergic to betamethasone dipropionate, clotrimazole and neomycin sulphate or any of the other ingredients of this medicine (listed in section 6).
- If your skin becomes irritated, or you develop an allergic reaction.

- On any other skin infections as it could make them worse, especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) around the mouth, nappy rash or other skin infections.

Warnings and precautions

If you have psoriasis, your doctor may want to review your treatment regularly. Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin.

Contact your doctor immediately if you, or your child, experience blurred vision or other visual disturbances.

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children.

In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

Children

Do not use this medicine on children under 12 years of age unless advised by your doctor. If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect your child's hormones. Rarely this may lead to:

- Delayed growth and development
- A moon face or rounding of the face
- A build-up of pressure around the brain which can produce
 - A bulging of the fontanelle (the soft spot in the top of the skull) in infants
 - A constant thumping headache
 - Blurred vision or other visual disturbances

Pregnancy and breast-feeding

Pregnancy

There is inadequate evidence of safety in pregnancy. Clotrimazole has shown no teratogenic effect in animals but is foetotoxic at high oral doses.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in human foetus. Hence BADRUF should only be used in

pregnancy if the benefit justifies the potential risk to the foetus and such use should not be extensive i.e. in large amounts or for long periods.

Breast-feeding

It is not known whether the components of BADRUF Cream are excreted in human milk and therefore caution should be exercised when treating nursing mothers.

3. How to take BADRUF Cream?

After cleaning the affected area, a sufficient quantity of BADRUF Cream should be applied to the affected area to form a thin even layer, two or three times daily. This treatment should be continued for several days after the disappearance of symptoms.

Adults and children over the age of 12 years. Topical administration twice daily for two weeks (tinea cruris, tinea corporis and candidiasis) or for four weeks (tinea pedis).

BADRUF Cream is not recommended for children under the age of twelve years.

Topical administration only.

4. Possible side effects

Skin atrophy or striae may occur following long term treatment with preparation containing corticosteroids.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

5. How to store BADRUF Cream?

- Keep BADRUF Cream and all the medicines out of reach and sight of children.
- Store BADRUF Cream at room temperature, 68°F to 77°F (20°C to 25°C).
- Throw away BADRUF Cream that is no longer needed or expired (out of date).
- Keep BADRUF in the container that it came in and keep the container tightly closed.
- Do not use BADRUF if the original seal over the container opening is broken or missing.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6. Contents of the pack and other information

What BADRUF Cream contains:

Active substance:

Clotrimazole, Betamethasone Dipropionate & Neomycin Sulphate

Other ingredients:

Sorbitol, Citric acid monohydrate, Sodium Methyl Paraben, Sodium Propyl Paraben, Propylene Glycol, Liquid Paraffin Heavy, Chlorocresol, Cetostearyl alcohol, Cetomacrogol – 1000 & Purified Water

What BADRUF Cream looks like and contents of the pack:

White coloured smooth cream filled in 30 gm Lami tube supplied in single carton along with package insert.

Supplier and Manufacturer:

Base Medico Pvt. Ltd.,

Survey No. 570, Village Tundav, Tal. Savli,

Dist. Vadodara - 391775, Gujarat, India.

Local Representative's Name & Address:

Basic Pharmaceutical & Herbal Health Care Ltd.,

24, Odelola Street, Surulere, Lagos, Nigeria.

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