

Betazol™ cream

betamethasone dipropionate 0.05% w/w + miconazole nitrate 2% w/w

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Betazol™ cream is and what it is used for

Betazol™ cream is a medicine which is used to treat inflamed conditions of the skin such as eczema and dermatitis which may be caused by infection with certain fungi and bacteria.

The cream contains the following ingredients:

- Miconazole nitrate 2% w/w: Is an antifungal which works by destroying both the fungus that causes the infection and some of the associated bacteria which may also be present.
- Betamethasone dipropionate 0.05% w/w: Is a topical steroid which reduces inflammation, swelling, redness and itching of the skin.

2. Before you use Betazol™ cream

Do not use Betazol™ cream if:

- You are allergic to any ingredient in Betazol™ cream (listed in section 6 Further information).
- You have any other skin problems such as cold sores, herpes, chicken pox or shingles. Only use it for the skin problem that you showed to the doctor.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Betazol™ cream.

Take special care with Betazol™ cream

Check with your doctor or pharmacist before using this medicine if:

- The inflamed skin is on your face. You should not use Betazol™ cream on your face, unless your doctor has told you.

Children

- The cream should not be used on young children for long periods of time (such as every day for several weeks) unless your doctor has told you.
- The cream should not be used on large areas of a child's body unless your doctor has told you.

Elderly patients

Medicines like Betazol™ cream can cause thinning of the skin when used for a long time without a break. Because thinning of the skin happens naturally in older people, this medicine should be used sparingly for no more than a few weeks in elderly patients. Only use it for as long as your doctor tells you.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

If you are pregnant or breast-feeding

Ask your doctor for advice before using this medicine if you are pregnant or breast-feeding. Your doctor will decide if you can use Betazol™ cream.

Driving and using machines

Betazol™ cream is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Betazol™ cream

Betazol™ cream contains cetostearyl alcohol, which can cause local skin reactions (e.g. contact dermatitis), chlorocresol and propylene glycol which can cause skin irritation.

3. How to use Betazol™ cream

Always use Betazol™ cream exactly as your doctor has told you.

Betazol™ cream is for use on your skin only.

You should check with your doctor or pharmacist if you are not sure.

How to apply the cream

- Each tube of Betazol™ cream is sealed. Use the cap to pierce the tube.
- Wash the infected area and dry it well.
- As many skin conditions are infectious, you should keep a towel and flannel for your own use. Do not share them so that you do not infect anyone else.
- Apply a small amount of Betazol™ cream to the affected area and rub it in gently until the cream has disappeared.
- Unless the infected skin is on your hands, wash your hands carefully after applying the cream to avoid spreading the infection to other parts of the body or to other people. Clothing which comes into contact with the infected areas should be washed and changed frequently.

How much to apply-adults and children

- Unless your doctor tells you differently, apply a small amount of Betazol™ cream to the affected area 2 times each day.
- If your skin problem does not improve in 7 days, tell your doctor.

4. Possible side effects

Like all medicines Betazol™ cream can cause side effects, although not everybody gets them.

Stop using Betazol™ cream and tell your doctor straight away if you notice the following. You may need medical treatment.

Sudden swelling of the face, lips, tongue, wheezing or shortness of breath. Severe irritation or reddening of the skin where the cream has been used, or other signs of severe allergy.

A few people may find that they suffer from some of the following side effects after using Betazol™ cream:

Allergic skin reactions, bacterial and secondary skin infections, acne, inflammation and/ or infection of the hair follicles, thinning of the skin, red marks with associated prickly heat, loss of skin colour, burning, stinging, itching, tingling, excessive hair growth and softening of the skin and stretch marks.

Tell your doctor or pharmacist if you notice or suspect any of the following side effects:

Uncommon side effects (affects fewer than 1 in 100 people)

Skin irritation, burning sensation, itchy skin, hives (also known as nettle rash, or urticaria), irritability.

Frequency not known:

Lighter patches of skin. Sensitivity reactions (such as rash) at the application site. Inflammation (contact dermatitis). If this occurs stop using the medicine.

Other side effects that may occur with topical corticosteroids are dry skin, skin irritation, dermatitis, dermatitis around the mouth, and small dilated blood vessels.

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

5. How to store Betazol™ cream

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use Betazol™ after the expiry date which is stamped on the pack and tube.

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.

6. Further information

What Betazol™ contains:

The active substances are miconazole nitrate (2% w/w) and betamethasone dipropionate (0.05% w/w).

The other ingredients are cetomacrogol 1000, cetostearyl alcohol, chlorocresol, sodium hydroxide, liquid paraffin, propylene glycol, white petroleum jelly and purified water.

What Betazol™ cream looks like and contents of the pack

Betazol™ cream is white to off white homogenous smooth cream. Betazol™ cream comes in aluminium collapsible tube of 30 grams.

Marketing Authorisation Holder and Manufacturer

Jamjoom Pharmaceuticals Co., Ltd.,

Jeddah, Saudi Arabia.

Tel: +966-12-6081111, Fax: +966-12-6081222.

Website: www.jamjoompharma.com

To report any side effect(s):

• Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
 - o Fax: +966-11-205-7662
 - o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
 - o Toll free phone: 8002490000
 - o E-mail: npc.drug@sda.gov.sa
 - o Website: www.sda.gov.sa/npc

• Other GCC States:

- Please contact the relevant competent authority.

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THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
 - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
 - The doctor and the pharmacist are experts in medicine, its benefits and risks.
 - Do not by yourself interrupt the period of treatment prescribed.
 - Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



Betazol™ Cream is a quality product manufactured by:



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