

PATIENT INFORMATION LEAFLET (PIL)

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

BETAMETHASONE 0.1%w/w CREAM

Betamethasone

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 health care provider.
- 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 any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

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1. WHAT BETAMETHASONE CREAM IS AND WHAT IT IS USED FOR

Betamethasone Cream contains the active ingredient Betamethasone.

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.

In adults and children, Betamethasone cream is used to treat skin problems: including eczema, all types of dermatitis and psoriasis of the scalp, hands, and feet. Eczema is a common skin disease, which causes the skin to become red and itchy. Dermatitis is inflammation of the skin. Psoriasis is a skin disease in which itchy, scaly, pink patches develop on the elbows, knees, scalp, and other parts of the body.

2. BEFORE YOU USE BETAMETHASONE CREAM

Do not use Betamethasone cream if you have any of the following conditions

- an allergy to betamethasone dipropionate or any of the other ingredients in this medicine.
- any other skin problem because Betamethasone dipropionate could make it worse, especially rosacea, acne, dermatitis around the mouth, genital itching, nappy rash, cold sores, chickenpox, shingles, or other skin infections. Ask your health care professional if you are not sure.

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 if you or your child experience blurred vision or other visual disturbances.
- This medicine should not be used under bandages or plasters.
- Side effects that may occur with oral or injectable 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.
- Do not smoke or go near naked flames – because of the risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a

serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children

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
- Puffiness 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, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

3. HOW TO USE BETAMETHASONE CREAM

Always use this medicine exactly as your health care provider has told you. Check with your healthcare professional if you are not sure.

Recommended dose

Usually for adults and children, a thin layer of Betamethasone cream should be rubbed into the affected area of skin twice a day.

Always follow the following instructions when using Betamethasone dipropionate cream:

- Do not use the cream on your face for more than 5 days.
- Do not use a large amount of cream on large areas of the body, open wounds, or areas of the body where joints bend for a long time (for example every day for many weeks or months).
- Avoid getting the cream in your eyes.

Use in children

Use as stated above. Do not use Betamethasone cream on any part of your child's body for more than 5 days. Do not put the cream under your child's nappy, as this makes it easier for the active ingredient of the medicine to pass through the skin and possibly cause some unwanted effects.

If you use more Betamethasone cream than you should

If you (or somebody else) accidentally swallows the cream, it should not cause any problems. However, if you are worried, you should see your doctor.

If you use the cream more often than you should, or on large areas of your body, it can affect some of your hormones. In children this may affect their growth and development. If you have not used the cream as you were told to do and have used it too often and/or for a long time, you should tell your doctor or pharmacist.

If you forget to use Betamethasone cream

If you forget to use your cream at the right time, use it as soon as you remember, then carry on as before.

If you stop using Betamethasone cream

If you have been using the cream for a long time and your skin problem seems to have got better, you should not suddenly stop using the cream. If you do, you may find that your skin becomes red and you may notice stinging or burning. To avoid this, you should speak to your doctor who will gradually reduce how often you need to use the cream until you stop treatment altogether.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Betamethasone Cream can cause side effects, although not everybody gets them. Most people find that when the cream is used correctly, it does not cause any problems. However, if you use the cream more than you should, particularly on your face, it can cause redness, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin, inflammation of the hair follicles, excessive hair growth, reduced skin pigmentation, allergic reactions, dermatitis (skin inflammation), other skin infections, thinning of the skin, red marks and blurred vision, please tell your health care provider.

Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE BETAMETHASONE CREAM

Keep all medicines out of the reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'Exp. Date' used for expiry date. The expiry date refers to the last day of that month.

Store below 30°C, in a dry place.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Betamethasone Cream contains:

The active substance is Betamethasone dipropionate.

What Betamethasone Cream looks like and contents of the pack:

25g cream in a tube, placed in a carton with insert.

Supplier and Manufacturer

Fidson Healthcare Plc,
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