AXCEL BETAMETHASONE CREAM

Betamethasone Valerate (0.1% w/w)

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What Axcel Betamethasone Cream is used for

Axcel Betamethasone Cream is used for the treatment of:

- Eczema, including atopic, infantile, discoid and stasis eczema
- Chronic itchy skin such as prurigo, neurodermatoses including lichen simplex and lichen planus.
- Psoriasis (skin disorder with raised, rough, reddened areas covered with dry, fine silvery scales).
- Seborrhoeic dermatitis (skin inflammation that mainly affects the scalp).
- Intertrigo (inflammation of the body folds).
- Contact sensitivity reactions.
- Discoid lupus erythematosus (recurring scaly rash).
- Generalised erythroderma (intense and usually widespread reddening and scaling of the skin due to inflammatory skin disease).
- Insect bites.
- Otitis externa (inflammation of the outer ear canal).

How Axcel Betamethasone Cream works

Betamethasone 17-valerate, a synthetic glucocorticoid, is thought to act by controlling the rate of

synthesis of protein. It works by reducing redness, inflammation, swelling, and irritation of the skin.

Before you use Axcel Betamethasone Cream

– <u>When you must not use it</u>

Do not use Axcel Betamethasone Cream:

- If you are allergy to any components in Axcel Betamethasone Cream.
- If you have Rosacea (skin disease that causes redness on your face).
- If you have acne.
- If you have peri-oral dermatitis (facial rash that causes bumps to develop around the mouth).
- If you have skin lesions caused by infection with viruses, fungi or bacteria.
- If it is not prescribed by a qualified doctor or dispensed by a qualified pharmacist for you.
- If you are pregnant, trying to get pregnant or think you may be pregnant.
- If you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it

Tell your doctor if:

• You are allergic to any medicines.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Axcel Betamethasone Cream

- How much to use

Direction for Use:

- Apply a small quantity to the affected skin 2 or 3 times daily until improvement occurs.
- It may then be possible to maintain improvement by applying once a day, or even less often.

• In the more resistant lesions such as the thickened plagues of psoriasis on elbows and knees, the effect of the preparation can be enhanced by occluding overnight the treatment area with polythene film, thereafter improvement can be maintained by regular application without occlusion.

- When to use it

Your doctor will decide when it is appropriate for you to use Axcel Betamethasone Cream according to the type of condition you have.

-How long to use it

Continue taking Axcel Betamethasone Cream for as long as doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Use the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not use a double dose to make up for the missed dose.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Axcel Betamethasone Cream.
- Tell your doctor immediately if you become pregnant while talking this medication.

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- Things you must not do

- Do not stop taking the medicine unless advised by your doctor or pharmacist.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Axcel Betamethasone Cream to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Long term continuous topical therapy and large dosage should be avoided where possible, particularly in infants and children when occlusive dressings are used or when skin folds are involved.
- Application to the eyelids may cause glaucoma (increased pressure in the eye).
- Avoid extensive use in pregnancy.
- If there is spread of infection, your doctor may discontinue the medicine and prescribe other medicine to treat the infection.

Side effects

Like all medicines, Axcel Betamethasone Cream 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 atropic changes in the skin such as stretch mark, thinning and dilatation of the superficial blood vessels.
- Hypercorticism (Cushing's syndrome, is a collection of signs and symptoms due to prolonged exposure to cortisol such as round-shaped face, weight gain, and skin that bruises easily).

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 portal.bpfk.gov.my (Consumers -> Reporting).

Storage and disposal of Axcel Betamethasone Cream

-Storage

Keep Axcel Betamethasone Cream out of reach of children. Keep container well closed. Store below 25°C. Protect from light.

-Disposal

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

Axcel Betamethasone Cream is smooth, white and water-miscible

-Ingredients

Active Ingredient: Betamethasone Valerate

Inactive Ingredients:

Dehydag wax "O", Sodium Dihydrogen Phosphate Anhydrous, Liquid Paraffin, Cremophor A6, Cremophor A25, Propylene Glycol, Chlorocresol and Purified Water.

-<u>MAL Number</u> MAL19890514AZ

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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