

AXCEL CLOBETASOL 0.05% OINTMENT

Clobetasol Propionate (0.05% w/w)

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What Axcel Clobetasol 0.05% Ointment is used for

Axcel Clobetasol 0.05% Ointment is used for short courses treatment of more resistant skin conditions such as:

- Psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales) excluding widespread plaque psoriasis.
- Resistant eczemas.
- Lichen planus (itchy reddish-purple flat-topped bumps on the wrists, forearms or lower legs).
- Discoid lupus erythematosus (causing scarring and increased sensitivity to sunlight).
- Other conditions which do not respond satisfactorily to less active steroids.

How Axcel Clobetasol 0.05% Ointment works

Clobetasol propionate is a highly active corticosteroid. It reduces the actions of chemicals in the body that causes inflammation, redness and itching.

Before you use Axcel Clobetasol 0.05% Ointment

-When you must not use it

Do not use Axcel Clobetasol 0.05% Ointment if:

- You are allergic or hypersensitive to any component of this medication.
- Children is under 1 year of age. If Clobetasol Propionate is required for use in children, it is

recommended that the treatment should be reviewed weekly.

- You have rosacea (a skin disease that causes redness and pimples), acne and perioral dermatitis (inflammation of the skin around the mouth).
- You have itching around the anus and genital.
- You have primary skin viral infection (e.g. herpes simplex and chicken pox).
- You have primarily infected skin lesions caused by fungi or bacterial infection. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic use of appropriate antimicrobial product.

-Before you start to use it

Tell your doctor if:

- You are pregnant or nursing your baby. Topical steroids should not be used extensively in pregnancy, such as in large amounts for prolonged periods.
- You have psoriasis.

-Taking other medicines

You should tell your doctor if you are taking any medicine as it may interact with your Axcel Clobetasol 0.05% Ointment.

How to use Axcel Clobetasol 0.05% Ointment

-How much to use

Direction for Use:

- Apply sparingly to the affected area once or twice daily until improvement occurs; normally within a few days in the more responsive conditions.
- Discontinue the therapy when control is achieved. If a longer course is required, it is recommended that treatment should not be continued for more than 4 weeks without the condition being reviewed. Repeated short course of the Clobetasol Propionate may be used to control exacerbations.
- A less potent preparation should be used if continuous steroid treatment is necessary. In very resistant lesions, especially

where there is skin thickening, the anti-inflammatory effect of Clobetasol Propionate can be enhanced by occluding the treatment area with polyethylene film.

- Overnight occlusion is usually adequate to bring about satisfactory response.
- Thereafter improvement can usually be maintained by application without occlusion.

-When to use it

Your doctor will decide when it is appropriate for you to use Axcel Clobetasol 0.05% Ointment according to the type of condition you have.

-How long to use it

- Use this medicine as stated in the leaflet without exceeding the recommended dosage.
- Follow any recommendations and advices from your doctor or pharmacist.

-If you forget to use it

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

-If you use too much (overdose)

You must inform your doctor immediately if you have used too much Axcel Clobetasol 0.05% Ointment.

In case of chronic overdosage or misuse, the features of hypercorticism may appear and topical corticosteroids should be discontinued.

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.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

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-Things you must not do

- Do not use your Axcel Clobetasol 0.05% Ointment more than the suggested frequency in a day.
- Do not apply with an occlusive dressing to large areas of the body.

-Things to be careful of

- Long term continuous topical application of corticosteroids should be avoid especially in children or when occlusive dressing is applied.
- The face, more than other areas of the body, may exhibit skin thinning changes after prolonged treatment with potent topical corticosteroids.
- Avoid contact with eyes.

Side effects

Like all medicines, Axcel Clobetasol 0.05% Ointment can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. When use of topical corticosteroids is prolonged, when the site of the application is covered with an occlusive dressing, or when large areas of the skin are involved, the absorption may result in sufficient systemic absorption to produce the features of hypercorticism. This effect is more likely to occur in infants and children, and if occlusive dressing are used. In Infants, the napkin may act as an occlusive dressing.

The following side effects have been reported:

- Hypercorticism (endocrine disorder caused by high levels of a hormone called cortisol in the blood).
- Hypersensitivity reactions. There are reports of pigmentation changes and excessive hair growth over the body with topical steroids.
- Skin changes such as stretch mark, thinning of the skin and dilatation of the superficial blood vessels.

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).

Storage and disposal of Axcel Clobetasol 0.05% Ointment

-Storage

Keep Axcel Clobetasol 0.05% Ointment out of reach children. Store below 30°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 Clobetasol 0.05% Ointment is translucent, waxy, water immiscible ointment.

-Ingredients

- Active Ingredient (s):

Clobetasol Propionate

- Inactive Ingredients:

Emulgin B2, Liquid Paraffin and White Soft Paraffin.

-MAL Number

MAL07124643AZ

Manufacturer and product registration holder

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

Date of revision

21/02/2018

Serial number

NPRA(R4/1)201217/00369