AXCEL SORFIC CREAM

Tretinoin (0.05% w/w)

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What Axcel Sorfic Cream is used

Axcel Sorfic Cream is used for the treatment of acne and promoting soft tissue formation.

How Axcel Sorfic Cream works

Tretinoin belongs to a class of medications called retinoids. It works by affecting the growth of skin cells. It promotes peeling of affected skin areas and unclogs pores.

Before you use Axcel Sorfic Cream

When you must not use it

Do not take Axcel Sorfic Cream if:

- You are taking other preparation especially desquamative (peeling) agents.
- You have acute eczema (an often itchy skin condition with redness, swelling, oozing of fluid, crusting which may lead to scaling).
- You have acute inflammation of the skin.
- You have rosacea (skin disease that give flushed appearance over the areas of the face).
- It is not prescribed by a qualified doctor or pharmacist for you.

Before you start to use it

Tell your doctor if:

- You are allergic to any medicines.
- You are taking any other medicines (including those not prescribed by your doctor).
- You are pregnant.

Taking other medicines

You should tell your doctor or pharmacist if you are taking the following medicine as it may interact with your Axcel Sorfic Cream:

Treatment with desquamative agents.

How to use Axcel Sorfic Cream

How much to use

This cream is for external use only.

- Axcel Sorfic Cream should be applied once a day, unless otherwise instructed by the physician.
- Clean the acne-affected skin area, then apply and spread Axcel Sorfic Cream with the finger.
- In case of too serious skin irritation the intervals between applications should prolonged.

When to use it

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

How long to use it

- Use this cream as stated in this leaflet without skipping or exceeding the frequency of application in a day and overall duration of application.
- Follow any recommendations and advises from your doctor or pharmacist on how long you need to take your medicine.
- To obtain beneficial therapeutic effects, generally a treatment of 8-12 weeks duration is required.

<u>If you forget to use it</u>

If you forget to use your cream at a certain time, use your cream as soon as you remember. However, if it is nearly time for your next application, skip the missed application.

If you use too much (overdose)

If, by mistake on a few occasions you use more than you should, do not worry. If you apply a lot or a lot is accidentally swallowed, it could make you ill. Talk to your doctor or go to the hospital as soon as possible.

While you are using it

Things you must do

- Discuss with your doctor or pharmacist the dos' and don'ts' while using this cream.
- Tell your doctor if unexpectedly you need to use any other medicines.
- Use the Axcel Sorfic Cream according to the recommended direction and duration.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

Things you must not do

- Do not use your Axcel Sorfic Cream more than the suggested frequency in a day.
- Do not apply multiple layers to the affected area.

Things to be careful of

- Avoid contact with eyes, mouth, nostril and mucous membrane (wet internal lining of the skin), otherwise thorough rinsing with water is recommended.
- Other topical peeling agents and the excessive use of soap should be avoided.
- Do no use on pregnant woman.

Side effects

Like all medicines, Axcel Sorfic 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:

- Reddening of the skin.
- Skin may become oedematous (swelling or puffiness) and blistered in more sensitive person.
- Acne may initially be worsened.
- Increased sensitivity to ultra violet light.
- Hypopigmentation (the loss of skin color) after prolonged treatment.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel:

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03-78835550, or visiting the website <u>portal.bpfk.gov.my</u> (Consumers -> Reporting).

Storage and disposal of Axcel Sorfic Cream

Storage

Keep Axcel Sorfic Cream out of reach of children.

Keep container well closed. Store your medicine below 25°C and protect from light.

Disposal

Do not use Axcel Sorfic Cream after the expiry date which is stated on the carton.

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 Sorfic Cream is light yellow and water-miscible perfumed cream.

Ingredients

Active Ingredient:

Tretinoin (Retinoic Acid)

Inactive Ingredients:

Vitamin E, D-Panthenol, Cremophor A6, Cremophor A25, Dehydag Wax "0", Chlorocresol, Sodium Dihydrogen Phosphate Anhydrous, Liquid Paraffin, Propylene Glycol, Fragrance P070, Purified Water.

MAL Number

MAL19900110A

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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