

AXCEL FUSIDIC ACID-B CREAM (NEW FORMULA)

Fusidic Acid / Betamethasone (as Valerate) (2.0% w/w/ 0.1% w/w)

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What Axcel Fusidic Acid-B Cream (New Formula) is used for

Axcel Fusidic Acid-B Cream (New Formula) is used to treat conditions where the skin is inflamed (eczema or dermatitis) and also infected by germs (bacteria).

How Axcel Fusidic Acid-B Cream (New Formula) works

Axcel Fusidic Acid-B Cream (New Formula) contains two different types of medicine. One medicine is called Fusidic acid. It is a type of antibiotic. The other medicine is called betamethasone valerate. It is a type of corticosteroid (steroid).

Axcel Fusidic Acid-B Cream (New Formula) works by the antibiotic killing germs that cause infections and corticosteroid help to reduce any swelling, redness or itchiness of your skin.

Your doctor may have prescribed this medication for another reason. Ask your doctor if you have any questions about why this medication has been prescribed for you.

Before you use Axcel Fusidic Acid-B Cream (New Formula)

-When you must not use it

- If you are allergic (hypersensitive) to Fusidic acid or betamethasone valerate

- If you are allergic (hypersensitive) to any of the other ingredients in this medicine.
- If you have perioral dermatitis. This is a red spotty rash around your mouth or chin.
- If you have skin conditions caused by a virus such as cold sores or chickenpox
- If you have skin condition caused by fungus
- If you have a skin condition called acne rosacea. This is the redness and inflammation over your nose and cheeks. Ask your doctor if you are unsure.
- If you have skin conditions caused by tuberculosis (TB) or syphilis.
- If you have skin conditions such as boils or spots.

Pregnancy or lactation

Please ask your doctor or pharmacist for advice before using Axcel Fusidic Acid-B Cream (New Formula):

- If you are pregnant, or think you are pregnant. You must not use your medicine for a long time or in large amounts. You must ask your doctor for advice.
- If you are breast-feeding.

-Before you start to use it

- Tell your doctor if you have allergies to any medicines, foods, preservatives or dyes.
- Tell your doctor if you plan to become pregnant or breastfeeding.

-Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

How to use Axcel Fusidic Acid-B Cream (New Formula)

- This medicine is only for using on your skin. Do not swallow it. Do not put it inside your body.
- Remove the cap. Check the seal is not broken before you first use the

cream. Then push the spike in the cap through the seal on the tube.

- Always wash your hands before using Axcel Fusidic Acid-B Cream (New Formula). Rub the medicine gently on the skin. If you use it on your face be careful to avoid your eyes.
- Unless you are using the cream to treat your hands, always wash your hands after using Axcel Fusidic Acid-B Cream (New Formula).

If you accidentally get any medicine in your eye, wash it out with cold water straight away. Then bathe your eye with eyewash if possible. Your eye may sting.

If you start to have any problems with your sight or your eye is sore, contact your doctor immediately.

-How much to use

Your doctor will tell you how much Axcel Fusidic Acid-B Cream (New Formula) to use.

-When to use it

Usually, you should use this medicine 2–3 times each day. To remind you to use the medicine it may help to use it when you do another regular action, such as brushing your teeth.

If you have been told to cover the skin with any dressings or bandages you may not need to use the medicine so often. Follow the advice of your doctor.

-How long to use it

Continue taking Axcel Fusidic Acid-B Cream (New Formula) for as long as your doctor recommends.

-If you forget to use it

If you forget to use this medicine, use it as soon as you remember. Then next use this medicine at the usual time.

If you have further questions about using this medicine, please ask your doctor or pharmacist.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of

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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

- Always use Axcel Fusidic Acid-B Cream (New Formula) exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- Please tell your doctor or pharmacist treating you that you are using Axcel Fusidic Acid-B Cream (New Formula).
- Please tell your doctor immediately if you become pregnant while using this medicine.

-Things you must not do

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

-Things to be careful of

- Take special care if you are going to use this medicine near your eyes or the eyes of a child. If the cream gets into the eye, this may lead to glaucoma.
- If you use the cream over a long time or in large amounts it may make the chance of getting any side effects higher. Also, your skin may get more sensitive to this medicine.
- You must not use the medicine for a long time on your face.
- Unless your doctor has told you to, you must not use Axcel Fusidic Acid-B Cream on open wounds or sensitive areas such as the nostrils, ears, lips or genitals.
- Unless your doctor has told you to, you must not use Axcel Fusidic Acid-B Cream on thin

skin, skin ulcers, broken veins or acne.

Side effects

Like all medicines, Axcel Fusidic Acid-B Cream (New Formula) can cause side effects although not everybody gets them.

You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction:

- You have difficulty breathing
- Your face or throat swell
- Your skin develops a severe rash.

Other possible side effects:

- Dilatation of the superficial blood vessels
- Thinning of the skin
- Stretch marks
- Glaucoma or an increase in pressure inside the eye. Signs are eye pain, red eye, decreased or cloudy vision
- Eye cataracts. Signs are cloudy or foggy vision
- Adrenal glands may stop working properly. Signs are tiredness, depression and anxiety.
- Excessive production of adrenal cortical hormones.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Axcel Fusidic Acid-B Cream (New Formula)

-Storage

- Keep out of the reach and sight of children.
- Do not use Axcel Fusidic Acid-B Cream (New Formula) after the expiry date on the carton.
- Do not keep the tube for more than 3 months after you first open it. Make a note of the date you first opened the tube.

- Store below 30°C. Keep container well closed. 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 Fusidic Acid-B Cream (New Formula) is white and water-miscible cream.

Axcel Fusidic Acid-B Cream (New Formula) comes in tubes of 5g and 15g.

-Ingredients

- Active Ingredients:

- Fusidic Acid (2.0% w/w)
- Betamethasone 17-valerate (0.1% w/w)

- Inactive Ingredients:

Chlorocresol, Liquid paraffin, Emulgin B2, Cetostearyl alcohol, White Soft Paraffin, Butylatedhydroxyanisole, Sodium Dihydrogen Phosphate Anhydrous and Purified water.

-MAL Number

MAL

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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