

# BACTAFUZ-B Fusidic Acid and Betamethasone Valerate Cream

Fusidic Acid (micronized) (2% w/w) and Betamethasone (as Valerate ester) 0.10% w/w

## What is in this leaflet

1. What BACTAFUZ-B Fusidic Acid and Betamethasone Valerate Cream is used for.
2. How BACTAFUZ-B works.
3. Before you use BACTAFUZ-B.
4. How to use BACTAFUZ-B.
5. While you are using it.
6. Side effects.
7. Storage and Disposal of BACTAFUZ-B .
8. Product Description.
9. Manufacturer and Product Registration Holder.
10. Date of revision.

### 1. What BACTAFUZ-B is used for

BACTAFUZ-B is used to treat conditions where the skin is inflamed (eczema or dermatitis) and also infected by germs (bacteria).

### 2. How BACTAFUZ-B works

BACTAFUZ-B 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).

BACTAFUZ-B 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.

### 3. Before you use BACTAFUZ-B

#### -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 skin condition caused by fungus.

- If you have skin conditions caused by a virus such as cold sores or chickenpox.
- If you have skin conditions such as boils or spots.
- If you have skin conditions caused by tuberculosis (TB) or syphilis.
- If you have perioral dermatitis. This is a red spotty rash around your mouth or chin
- 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.

#### Pregnancy and lactation

*Pregnancy:* Fusidic Acid and Betamethasone Valerate Cream should not be used during pregnancy unless clearly necessary.

*Breast-Feeding:* Fusidic Acid and Betamethasone Valerate Cream can be used during breast -feeding but should not be applied on the breasts to avoid accidental ingestion by the infant.

#### -Before you start to use it

- Tell your doctor if you have allergies to any other 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.

### 4. How to use BACTAFUZ-B

- 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 BACTAFUZ-B. 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 BACTAFUZ-B.

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

Uncovered lesions: 2 to 3 daily applications.

Covered lesions: less frequent applications may be adequate.

#### -When to use it

Use as directed by your doctor or pharmacist.

#### -How long to use it

Continue taking BACTAFUZ-B 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 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.

### 5. While you are using it

#### -Things you must do

- Always use BACTAFUZ-B exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

# BACTAFUZ-B Fusidic Acid and Betamethasone Valerate Cream

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- Please tell your doctor or pharmacist treating you that you are using BACTAFUZ-B.
- 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.
- Do not give BACTAFUZ-B 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 BACTAFUZ-B 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 BACTAFUZ-B on thin skin, skin ulcers, broken veins or acne.

## 6. Side effects

Like all medicines, BACTAFUZ-B can cause side effects although not everybody gets them.

Important side effects to look out for:

- Hypersensitivity (allergic reactions)
- Dermatitis contact & acneiform (inflammation of skin)
- Perioral Dermatitis (red spotty rash around mouth or chin)

- Eczema (inflammation of skin) (condition aggravated)
- Skin burning sensation
- Pruritus (itchy skin)
- Dry Skin
- Erythema (redness of skin)
- Urticaria (skin rash)
- Rash (including rash erythematous and rash generalized)
- Application site pain, irritation, swelling and vesicles.
- Adrenal suppression especially during prolonged topical administration
- Raised intra-ocular pressure, glaucoma and cataract (eye conditions)
- Atrophy
- Skin striae (scarring of skin)
- Telangiectasia (dilated blood vessels on skin)
- Rosacea (redness of skin)
- Hypertrichosis (excessive hair growth)
- Hyperhidrosis (excessive sweating)
- Depigmentation
- Ecchymosis (discoloration of skin)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

## 7. Storage and Disposal of BACTAFUZ-B Cream

- Storage

- Keep medicine out of reach of children.
- Do not use BACTAFUZ-B after the expiry date on the carton.
- Store below 30°C, protected from light
- Do not freeze

- Disposal

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need any more. If you do this you will help protect the environment.

## 8. Product Description

- What it looks like

A white to off white smooth, homogeneous cream  
BACTAFUZ-B comes in aluminium tubes of 15g.

- Ingredients

- Active ingredient

- Fusidic Acid 2.0% w/w
- Betamethasone (as Valerate) 0.10% w/w

- Inactive ingredients

- Macrogol Cetostearyl ether
- Cetostearyl alcohol
- Chlorocresol
- Liquid paraffin
- Sodium dihydrogen phosphate
- White soft paraffin
- Purified water
- Sodium hydroxide

Important information about some of the ingredients of BACTAFUZ-B

BACTAFUZ-B contains:

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and Chlorocresol may cause allergic reactions.

Please ask your doctor if you are worried about any of the ingredients in this medicine.

- MAL number:

MAL\*\*\*\*\*

## 9. Manufacturer

Encube Ethicals Pvt. Ltd.  
Plot No. C1, Madkaim Ind. Estate,  
Madkaim,  
Post: Mardol, Ponda, Goa-403 404,  
India

## Product Registration Holder

Pahang Pharmacy Sdn. Bhd.  
Lot 5979, Jalan Teratai,  
5 1/2 Miles off Jalan Meru, 41050  
Klang, Selangor, Malaysia

## 10. Date of revision

12/03/2019

Serial number  
NPRAR(2)19/13