

15a



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keen this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. In this leaflet Fusimed-B cream will be called Fusimed-B

What is in this leaflet:

- What Fusimed-B is and what it is used for
- What you need to know before you use Fusimed-B
- How to use Fusimed-R
- Possible side effects
- How to store Fusimed-B
- Contents of the pack and other information

WHAT Fusimed-B IS AND WHAT IT IS USED FOR

Fusimed-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). The two medicines work at the same time in different ways. Fusimed-B works by:

- The antibiotic killing germs (bacteria) that cause infections.
- The corticosteroid reducing any swelling, redness or itchiness of your skin.
- · Fusimed-R is used to treat:
- Conditions where the skin is inflamed (eczema or dermatitis) and infected, or might become infected, by germs (bacteria).

WHAT YOU NEED TO KNOW BEFORE YOU USE Fusimed-B

Do not use Fusimed-B

- · If you are allergic (hypersensitive) to fusidic acid/sodium fusidate or betamethasone valerate or any of the other ingredients of this medicine
- . To treat infections caused by a fungus, such as athlete's foot or ringworm
- To treat a skin condition caused by a virus, such as cold sores or chicken pox.
- · To treat skin conditions caused only by bacteria, such as boils or spots.
- To treat skin conditions caused by tuberculosis(TB).
- . To treat a condition called perioral dermatitis. This is a red spotty rash around your mouth or chin.
- To treat a skin condition called rosacea. This is redness and inflammation over your nose and cheeks. Ask your doctor if you are unsure.

Warnings and precautions

Take special care with Fusimed-B Do not use for a long time, continuously (without stopping), as this medicine contains a steroid. Do not use the cream on yourself or a child for more than 2 weeks, this is to avoid bacteria becoming resistant to the antibiotic and to avoid the steroid causing you side effects.

- Avoid getting the cream in or near your eyes (e.g. accidentally from your hands) as it could damage them
- . Do not use a large amount of the cream (follow your doctor's instructions). Do not use the cream on thinning skin, skin ulcers, acne (spots) or in
- skin folds (e.g. under breasts, groin area or armpits)
- Do not use the cream under bandages or dressings (as this increases the action of steroids)
- · Take special care if you are going to use this medicine on a child, as children are more sensitive to steroids.
- Do not use on the face as betamethasone is a strong steroid.
- . Take care if you have been or are susceptible to infections. Do not use the cream on large areas of your body.
- Do not use the cream on open wounds or mucous membranes (e.g. nose or mouth). Other medicines and Fusimed-B

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are pregnant or think you might be pregnant. Fusimed-B cream should not be used during pregnancy unless you are told to do so by your doctor

If you are breast-feeding. Fusimed-B may be used by women who are breast-feeding, but the cream should not be applied to the breast.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machinery. Check with your doctor if you feel any side effect that may stop you from driving or using machinery

Important information about some of the ingredients in Fusimed-B

How to use Fusimed-B

Always use fusimed-B exactly as your doctor has told you. Check with your pharmacist if you are not sure.

How to Put on Fusimed-R

This medicine is only for using on your skin or the skin of a child. Do not swallow it. Always wash your hands before using Fusimed-B 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 in the tube. Rub the cream gently on the skin. If your doctor has told you to use it on your face be very careful to avoid your eyes. If you accidentally get any medicine in your eye wash it out with cold water straight away. Then bath your eyes with eyewash if possible. Your eye may sting, If you start to have any problems with your sight or your eyes are sore, contact your doctor immediately. Unless you are using the cream to treat your hands, always wash your hands after using Fusimed-B.

How much Fusimed-B to use

- Your doctor will tell you how much Fusimed-B to use.
- . The usual treatment time is up to two weeks. Ask your doctor before using this medicine for any longer.
- · You should notice your skin improve after just a few days of using the cream. If there is no improvement after seven days you should stop
- the cream and go back to your doctor.
- · Usually you should use this cream twice each day. Use it in the morning and evening.

- · 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 e.g. a nappy on a baby may act as a dressing. Follow the advice of your doctor.

HOW MUCH CREAM SHOULD I USE?

If your doctor has given you specific instructions about the amount of cream to use, then keep to this advice. If not, the following guide will help you to use the correct amount. Use your index finger (first finger) as a measure. Squeeze the cream from the tube along your index finger from the tip to the first joint as shown in the diagram on the left. This amount of cream is one fingertip unit. One fingertip unit is the amount of cream squeezed along your index finger to the first joint.

For adults

The diagram below shows how much cream you need to cover different areas of your body. If you find you need slightly more or less cream than indicated, do not worry as this is only a general guide.

Hee in Children

- The above quide is for adult use only and is not suitable for use in children.
- Do not use this medicine on a child for more than 2 weeks as it contains a steroid.

If you forget to use Fusimed-B

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 any further questions about using this medicine, please ask your doctor or pharmacist.

What medical checks will you have?

Normally no special medical checks are needed if the cream is used as intended.

If you have any further questions about the use of this product, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not every body gets them. The most common side effect is itching

Important side effects to look out for:

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

- · You have difficulty in breathing
- . Your lips and mouth start to tingle or swell
- · Your face or throat swell
- · Your skin develops a severe rash

Other possible side effects:

Other possible side effects which are less serious can also occur. You should tell your doctor about these as soon as possible

Uncommon (probably affects up to 1 in 100 people) Itchy rash and skin inflammation in the area where the medicine is used (contact dermatitis)

- Worsening of your eczema
- · Skin burning feeling
- · Itchy skin

Dry skin

Pain or skin irritation in the area where the medicine is used. HOW TO USE Fusimed-B Rare (probably affects up to 1 in 1,000 people)

- · Redness of the skin · Hives
- Rash
- · Swelling in the area where the medicine is used

· Redness of the skin due to widening of the small blood vessels

The following additional side effects are known to be caused by steroids and are more likely to occur after longer term use:

- · Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety
- · An increase in pressure inside the eye (signs are eye pain, red eye, decreased or cloudy vision) or eye cataracts (signs
- are cloudy or foggy visions).
- · Thinning of the skin
- · Skin rash with inflammation or swelling (allergic contact dermatitis) or with pimples like acne.
- · Red rash around the mouth (perioral dermatitis)
- · Appearance of surface veins or stretch marks
- Redness and inflammation over your nose and cheeks (rosacea)
- · Redness.
- · Increased hair growth on the body
- · Excessive sweating. Lightening of skin colour
- Red blood spots under your skin.

Other medicines and Fusimed-B

If you notice the above or any other changes in your health while using this medicine, tell your doctor. If any of the side effects become serious, or if you notice any side effects not listed here, please tell your doctor or pharmacists soon as possible.

INSTRUCTIONS:

Use as directed by the physician. Keep out of the reach of children. Protect from light & freezing. Store at temperature between 20°C to 25°C.





