

FUSATE H CREAM

Fusidic acid 20mg and Hydrocortisone acetate 10mg

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What FUSATE H CREAM used for

FUSATE H CREAM combines the antibacterial action of fusidic acid (antibiotic) with the anti-inflammatory effect of hydrocortisone acetate (corticoid).

It is used for the topical treatment of infected atopic dermatitis (commonly known as eczema, a skin disease accompanied by inflammation, reddening, exudation or scabs and itching, frequently of an allergic origin). Because of its hydrocortisone content, Fusate-H Cream is particularly appropriate in cases where a milder corticosteroid (a group of steroid hormones that are produced in the adrenal cortex of vertebrates, and the synthetic substances with like properties). It is indicated, including milder inflammatory dermatoses on the face and children's skin. Fusate-H Cream is cosmetically acceptable for use on the face and hands and convenient for use in the line of joint, and armpits area.

How FUSATE H CREAM works

The Fusidic acid killing germs (bacteria) mainly gram positive organisms that causes infections.

The corticosteroid reducing any swelling, redness or itchiness of your skin. It is used to treat Conditions where the skin is inflamed (eczema or dermatitis) and infected, or might become infected, by germs (bacteria).

Before you use FUSATE H CREAM

When you must not use it

-if you are allergic (Hypersensitive) to fusidic acid/sodium fusidate or hydrocortisone acetate

As this medicine contains a steroid do not use

- To treat skin infections caused by a fungus, such as athlete's foot or ringworm.
- To treat skin conditions 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.

Pregnancy and lactation

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.

FUSATE H CREAM should be used with caution during pregnancy.

FUSATE H CREAM can be used during breast-feeding, but it is recommended to avoid using it on the breast.

Before you start use it

- FUSATE H CREAM should be applied with care when used near the eyes. Must not enter the eyes.
- The use of FUSATE H CREAM is limited to 2 weeks. Long-term treatment may result in risk of increased side effects and risk of antibiotic resistance, e.g. your skin may become thin
- FUSATE H CREAM might mask potential symptoms of infections
- FUSATE H CREAM might make you more susceptible to infection, aggravation of existing infection and activation of latent infection

Children and adolescents

FUSATE H CREAM should be used with care in children.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from pharmacy, supermarket or health food shop without a prescription.

How to use FUSATE H CREAM

How much to use

The usual treatment time is about two weeks.

Ask your doctor before using this medicine for any longer.

Usually you should use this cream two or three times each day.

For covered lesions, less frequent application may be adequate

When to use it

Two to three times daily. Use as directed by your doctor or pharmacist.

How long to use it

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 using the cream and go back to your doctor.

Do not use for a long time, continuously (without stopping), as this medicine contains a steroid.

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Do not use the cream on yourself or a child for more than 2 weeks.

If you forget to use

In case you forget to apply the cream at your regular time, apply it as soon as possible and continue as usual.

If you use too much (overdose)

If you have applied more cream than you should, consult your doctor or pharmacist.

While you are using it.

Things you must do

- Always wash your hands before using FUSATE H CREAM
- 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 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.
- Unless you are using the cream to treat your hands, always wash your hands after using FUSATE H CREAM

Things you must not do

This medicine is only for using on your skin or the skin of a child. Do not swallow it

Things to be careful of

- 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 e.g your skin may become thin.

- Do not use the cream on large areas of your body.
- Do not use the cream under bandages or dressings (as this increases the action of steroids)
- Avoid getting the cream in or near your eyes (e.g. accidentally from your hands) as it could damage them or cause an increased pressure in your eyes.
- 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).

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects

Reaction at the application site (e.g. skin irritation, skin burning or itching)

Uncommon side effects

- hypersensitivity
- contact dermatitis
- aggravation of eczema
- rash

Other side effects caused by prolonged treatment of mild corticoids like hydrocortisone include:

- thinning of the skin (skin atrophy)
- dermatitis
- stretch marks (striae)
- dilatation of the small blood vessels on the skin
- persistent facial redness (rosacea)
- redness of the skin (erythema)
- depigmentation
- excessive growth of the hair (hypertrichosis)
- excessive sweating (hyperhidrosis)
- bruises
- Systemic side effects of mild corticosteroids, like hydrocortisone, include adrenal suppression

especially during prolonged topical administration.

- complications if administered too close to the eye (i.e. raised intra-ocular pressure and glaucoma)

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. If these side effects get serious, or if you notice any other side effect not listed in this leaflet, please tell your doctor or pharmacist.

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 portal.bpfk.gov.my (Consumer→Reporting)

Storage and Disposal of FUSATE H CREAM

Storage

Store in a cool dry place below 30°C. Keep medicine out of reach of children. For external use only.

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

A white to off white, smooth cream

Ingredients

Active Ingredients:

Fusidic acid 20mg or 2.0% w/w
Hydrocortisone acetate 10mg or 1.0% w/w

Inactive ingredients

- Cetostearyl Alcohol
- White Soft Paraffin
- Liquid Paraffin

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- Polysorbate 80
- Butylated Hydroxy Anisole
- Glycerin
- Potassium sorbate
- Purified Water

MAL number:

Manufacturer and Product

Registration Holder:

Noripharma Sdn. Bhd.
Lot 5030, Jalan Teratai,
5 ½ Miles off Jalan Meru
41050 Klang, Selangor

Date of Revision

15/12/2016