

PATIENT INFORMATION LEAFLET (PIL)

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

H-CORT 1%w/w CREAM

Hydrocortisone

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider. - This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What H-CORT CREAM is and what it is used for
2. Before you use H-CORT CREAM
3. How to use H-CORT CREAM
4. Possible side effects
5. How to store H-CORT CREAM
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1. WHAT H-CORT CREAM IS AND WHAT IT IS USED FOR

H-Cort Cream belongs to a group of medicines called topical corticosteroids. These work by calming the inflammation that occurs during certain skin conditions or reactions. H-Cort cream may be used for treating various skin conditions including: Eczema; Dermatitis including intertrigo (irritation between skin folds); Insect bite reactions; Inflammation of the external ear (otitis externa); Prurigo nodularis: A long-term skin condition where very itchy lumps appear; Neurodermatoses: A long-term skin condition where itchy skin becomes thick due to scratching; Nappy rash, (if there is no infection present, or existing infection is being treated with appropriate antibiotics).

2. BEFORE YOU USE H-CORT CREAM

Do not use H-CORT CREAM if you

- are **allergic** (hypersensitive) to hydrocortisone or any of the other ingredients of this medicine
- have any other **skin infection** such as athlete's foot (tinea pedis), chickenpox (varicella) or shingles (Herpes zoster), coldsores (Herpes simplex), impetigo, ringworm or thrush, infected lesions, ulcerative conditions, red appearance on face, peri-oral dermatitis or acne.

Take special care with H-CORT CREAM

Talk to your health care provider before you start to use this medicine if you:

- have psoriasis; the condition may become worse after stopping long-term treatment
- will be applying the cream to your face, particularly around the eyes. This cream should not be used for long on the face as it may damage the facial skin.
- will be using the cream for the treatment of dermatitis or nappy rash on children and infants. Treatment in infants should be limited to a maximum of seven days.
 - are applying the cream under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to

accidentally end up using too much cream.

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- have a **skin infection**. If the condition appears to be getting worse despite using antibiotics prescribed, stop using the cream and contact your doctor

Caution should be taken to keep away from the eyes. Contact your health care provider if you experience blurred vision or other visual disturbances.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

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 health care provider for advice before using this medicine.

3. HOW TO USE H-CORT CREAM

Always use H-Cort cream exactly as your health care provider has told you. Check with your health care provider if you are not sure.

For application to the skin.

The recommended dose is:

- Adults: Gently apply a thin layer of cream to the affected area(s) two or three times a day.
- Children and infants: Gently apply a thin layer of cream to the affected area(s) two or three times a day. The smaller the child, the less you will need to use. A course of treatment for a child should not normally last more than 7 days - unless your doctor has told you to use it for longer.

If you use more Hydrocortisone cream than you should

- Do not use the cream more often or for longer than your doctor tells you to.
- Do not use larger quantities than as directed, as this will increase the possibility of side effects.
- If you accidentally use too much on a few occasions do not worry.
- If you squeeze out too much cream, wipe off the excess with a paper towel. Do not use the cream under airtight dressings (such as plasters) or nappies, as too much hydrocortisone may be absorbed and may result in adverse effects upon adrenal gland function.

If you forget to use Hydrocortisone Cream

If you forget to use the cream, apply it as soon as you remember, unless it is nearly time to apply the next dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, H-CORT CREAM can cause side effects, although not everybody gets them. Most patients using Hydrocortisone Cream will have no problems when used in the correct amount for the prescribed time. If the following happens, stop using the cream and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives). This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Other effects which may occur:

- A change in the colour of skin, or increased growth of hair in areas where the cream is used
- Contact dermatitis: localised rash or irritation to the skin.
- The skin may become thinner when used in the nappy areas of children where conditions are moist

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- If H-Cort Cream is used often over a large area of skin or for a long time, especially under dressings, adverse effects on adrenal gland function are more likely. These effects are also more likely in children and infants
- Prolonged use, especially on sensitive areas including skin folds, may result in thinning of the skin, widening of the blood vessels, stretch marks and may suppress the functioning of the adrenal gland
- Blurred vision. This side effect has been reported, but the frequency for it to occur is not known. If your condition becomes worse during treatment, you may have an allergy to one of the ingredients of the cream or an infection. Stop using the cream and tell your doctor as soon as possible.

Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE H-CORT CREAM

Keep all medicines out of the reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'Exp. Date' used for expiry date. The expiry date refers to the last day of that month. Store below 30°C, in a dry place.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION**What H-CORT CREAM contains:**

- The active pharmaceutical ingredient is hydrocortisone.

What H-CORT CREAM looks like and contents of the pack:

25g cream in a tube, placed in a carton with insert.

Supplier and Manufacturer

Fidson Healthcare Plc

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