Package leaflet: Information for the patient

Hydrocortisone Cream

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep 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 only. 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Hydrocortisone Cream is and what it is used for
2. What you need to know before you use Hydrocortisone Cream
3. How to use Hydrocortisone Cream
4. Possible side effects
5. How to store Hydrocortisone Cream
6. Contents of the pack and other information

1. What Hydrocortisone Cream is and what it is used for

Hydrocortisone Cream contains a medicine called hydrocortisone. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.
Hydrocortisone Cream is used to:
- help reduce the redness and itchiness of certain skin problems. These skin problems include eczema, dermatitis or insect bites
- help reduce inflammation of the outer ear.

2. What you need to know before you use Hydrocortisone Cream

Do not use Hydrocortisone Cream:
- if you are allergic to hydrocortisone, or any of the other ingredients of this medicine (listed in section 6).
- to treat any of the following skin problems, it could make them worse:
  - viral infections, such as cold sores, herpes or chicken pox
  - fungal infections, such as ringworm, athletes foot or thrush
  - skin blisters or sores that are caused by an infection.

If any of the above apply to you, speak to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before using Hydrocortisone Cream
- if you 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.

If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.
If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your prescriber unless your prescriber has previously advised you

to so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Contact your doctor 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.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

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.

Hydrocortisone Cream contains: Chlorocresol, which may cause allergic reactions; and **Cetostearyl alcohol**, which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Hydrocortisone Cream

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine
- You usually apply a small amount of Hydrocortisone Cream 2 to 3 times a day. This may be reduced as your skin begins to get better.
- This cream is for use on your skin only.
- Do not use on large areas of the body for a long time (such as every day for many weeks or months) - unless your doctor tells you to.
- If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- If your skin problem does not improve, talk to your doctor.

Guidance on how to apply the cream
1. Wash your hands.
   Gently rub the correct amount of cream into the skin until it has all disappeared. You can measure how much Hydrocortisone Cream to use with your fingertip. This picture shows one fingertip unit.

[Pictogram]

2. Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

For an adult
You should find that:
- two fingertips of cream will cover both hands or one foot
- three fingertips of cream will cover one arm
- six fingertips of cream will cover one leg
- fourteen fingertips of cream will cover the front and back of the body.

Do not worry if you find you need a little more or a little less than this. It is only a rough guide.
[Pictogram]

For a child
- The smaller the child the less you will need to use.
- A child of 4 years needs about a third of the adult amount.

- 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 apply Hydrocortisone Cream to your face
You should only apply the cream to your face if your doctor tells you to. The cream should not be used for too long as the skin on your face thins easily.

If you use more Hydrocortisone Cream than you should
If, by mistake on a few occasions you use more than you should, do not worry. If you apply a lot or if a lot is accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible.

If you forget to use Hydrocortisone Cream
If you forget to apply your cream, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

If you stop using Hydrocortisone Cream
If you use Hydrocortisone Cream regularly make sure you talk to your doctor before you stop using it.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Hydrocortisone Cream is classed as a mild corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

4. Possible side effects

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

STOP using Hydrocortisone Cream and tell your doctor as soon as possible if:
- you find that your skin condition gets worse or becomes swollen during treatment. You may be allergic to the cream, have an infection or need other treatment.

Other side effects you may notice when using Hydrocortisone Cream include:
- irritation or itching where the cream is applied
- increased hair growth and changes in skin colour
- blurred vision.

Side effects if you use Hydrocortisone Cream for a long time, you use a lot each time you apply it, or you apply it under an airtight dressing or a nappy:
- thinning of your skin and it may also damage more easily
- weight gain, rounding of the face and high blood pressure. These are more likely to happen in infants and children.

Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydrocortisone Cream

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube and on carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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

6. Contents of the pack and other information

What Hydrocortisone Cream contains

- The active substance is hydrocortisone. Each 1 g contains:
  - 5 mg of hydrocortisone (0.5% w/w),
  - 10 mg of hydrocortisone (1% w/w), or
  - 25 mg of hydrocortisone (2.5% w/w).
- The other ingredients are:
  chlorocresol, cetomacrogol 1000, cetostearyl alcohol, white soft paraffin, liquid paraffin, sodium acid phosphate, phosphoric acid, sodium hydroxide and purified water. (See end of section 2 for further information on chlorocresol and cetostearyl alcohol).

What Hydrocortisone Cream looks like and contents of the pack
Within each carton is a tube with a plastic screw cap, which contains 15 g, 30 g or 50 g of cream.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Chemidex Pharma Ltd, trading as Essential Generics, 8a Crabtree Road, Egham,
Surrey, TW20 8RN, United Kingdom.

Manufacturer
Purna Pharmaceuticals NV, Rijksweg 17, 2870 Puurs, Belgium.

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