

Alfacort

Cream, Ointment

1% Hydrocortisone
Topical corticosteroid

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 **Alfacort** is and what it is used for
2. What you need to know before you use **Alfacort**
3. How to use **Alfacort**
4. Possible side effects
5. How to store **Alfacort**
6. Further information

1. What **Alfacort** is and what it is used for

Alfacort belongs to a group of medicines called topical corticosteroids. These work by calming the inflammation that occurs during certain skin conditions or reactions.

Alfacort 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. What you need to know before you use **Alfacort**

Do not use **Alfacort 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), cold sores (Herpes simplex), impetigo, ringworm or thrush, infected lesions, ulcerative conditions, red appearance on face, peri-oral dermatitis or acne.

Warnings and precautions

Talk to your doctor or pharmacist 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 **Alfacort** to your face, particularly around the eyes. This medicine should not be used for long on the face as it may damage the facial skin
- will be using the **Alfacort** 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 **Alfacort** 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 of cream or ointment.
- have a **skin infection**. If the condition appears to be getting worse despite using antibiotics prescribed, stop using the **Alfacort** and contact your doctor

Caution should be taken to keep away from the eyes. 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

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 using this medicine.

Information about some of the ingredients of **Alfacort**:

Alfacort cream contains Cetostearyl alcohol which may cause local skin reactions such as contact dermatitis and chlorocresol which may cause allergic reactions, in some people.

3. How to use **Alfacort**

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

For application to the skin.

The recommended dose is:

- Adults – gently apply a thin layer of cream or ointment to the affected area(s) two or three times a day.
- Children and infants – gently apply a thin layer of cream or ointment to the affected areas(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 **Alfacort** than you should

- Do not use the cream or ointment 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 accidentally swallow some cream or ointment, small amounts are not harmful.
- If you squeeze out too much cream or ointment, wipe off the excess with a paper towel. Do not use the cream or ointment, 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 **Alfacort**

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

4. Possible side effects

Like all medicines, **Alfacort** can cause side effects, although not everybody gets them. Most patients using **Alfacort** will have no problems when used in the correct amount for the prescribed time.

If the following happens, stop using **Alfacort** 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 cream or ointment 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.
- if **Alfacort** 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 ointment, or an infection. Stop using the **Alfacort**, and tell your doctor as soon as possible.

Reporting of side effects

You can also report side effects directly via:

• Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

Fax: +966-11-205-7662

Call NPC at +966-11-2038222,

Exts: 2317-2356-2340

Reporting Hotline: 19999

E-mail: npc.drug@sfd.gov.sa

Website: www.sfda.gov.sa/npc

• Other GCC States:

Please contact the relevant competent authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store **Alfacort**

- Keep out of the reach and sight of children.
- Do not use **Alfacort** after the expiry date which is stated on the carton and on the tube.
- Store below 30°C. Best use within one month of opening.
- Do not use **Alfacort** if you notice any visible sign of deterioration.
- 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.

6. Further Information

What **Alfacort** contains

Alfacort Cream

Alfacort cream contains 1% hydrocortisone.

Excipients: Propylene glycol, chlorocresol, liquid paraffin, cetomacrogol 1000, cetostearyl alcohol, white soft paraffin, sodium phosphate monobasic, methyl paraben, propyl paraben and purified water.

Alfacort Ointment

Alfacort ointment contains 1% hydrocortisone.

Excipients: White soft paraffin, liquid paraffin and sorbitan sesquioleate.

What are the available packs of **Alfacort**

Alfacort cream or ointment is available in tubes containing 15g each.

THIS IS A MEDICAMENT

- Medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of the children

**Council of Arab Health Ministers,
Union of Arab Pharmacists**

Any information? Call (971) 800-4994, U.A.E.



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