

PACKAGE LEAFLET: INFORMATION FOR THE USER

Haelan Cream 0.0125% w/w
Fludroxycortide



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 doctor or pharmacist.
- 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Haelan Cream is and what it is used for
2. Before you use Haelan Cream
3. How to use Haelan Cream
4. Possible side effects
5. How to store Haelan Cream
6. Further information

1. WHAT HAE LAN CREAM IS AND WHAT IT IS USED FOR

Haelan Cream is a white cream for application to the skin. Haelan Cream belongs to a group of medicines called topical steroids and is used to treat skin conditions such as eczema and dermatitis of all types, especially when the skin is moist or weeping. Haelan Cream can be used in adults and children.

2. BEFORE YOU USE HAE LAN CREAM

Do not use Haelan Cream for

- skin tuberculosis
- rosacea of the face
- acne
- dermatitis around the mouth
- itchiness of the genitals or anus
- skin conditions in babies including eczema or napkin rash
- bacterial skin infections such as impetigo
- viral skin infections such as cold sores
- fungal skin infections such as athlete's foot

Do not use Haelan Cream if you are allergic (hypersensitive) to fludroxycortide or any of the other ingredients in Haelan Cream (see section 6).

Take special care with Haelan Cream

- The cream should not be used on or near your eyes or inside your mouth.
- Do not use Haelan Cream for long periods of time and do not cover it tightly under dressings or clothes.
- Do not use Haelan Cream on large areas of damaged skin or in skin folds such as the armpits or groin area.
- Do not use Haelan Cream on your face for more than five days and do not cover it up tightly.
- If you have a skin infection or think you have a skin infection, tell your doctor.
- Do not use Haelan Cream on children's skin for more than five days and do not cover it up tightly.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Do not use Haelan Cream if you are pregnant, think you could be pregnant, are planning to become pregnant or are breast-feeding. Please ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Haelan Cream

Haelan Cream contains cetyl alcohol which may cause local skin reactions such as contact dermatitis and propylene glycol which may cause skin irritation.

3. HOW TO USE HAE LAN CREAM

Always use Haelan Cream exactly as your doctor has told you. Check the label for how to use your medicine and how often to use it. Only put the cream on the parts of your skin your doctor wants to treat. You should check with your doctor or pharmacist if you are not sure.

Usual dose

Only use Haelan Cream on your skin. Do not put it in your mouth or eyes.

Apply the cream gently to the affected area of skin two or three times each day. If you are elderly your skin may be thin so you will need to apply the cream sparingly.

If your doctor has told you to cover the skin tightly where you are using Haelan Cream, you should only have to cover a small area.

If you forget to use Haelan Cream

If you forget to use Haelan Cream do not worry, just put on the next application when it is due.

If accidentally swallowed, contact your nearest hospital casualty department or tell your doctor immediately.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Haelan Cream can cause side effects, although not everybody gets them.

Some patients may have one or more of the following side effects in the area where they apply Haelan Cream

- | | |
|--|--|
| • Burning, itching, irritated or dry skin. | • Inflammation at the bottom of skin hairs. |
| • Excess hair growth. | • Acne pimples. |
| • Pale skin. | • Dermatitis around the mouth. |
| • Allergic contact dermatitis. | • Limp, flabby or thin skin where the cream was. |
| • Skin softening. | • Skin infections may get worse. |
| • Red spots or lines on the skin. | • Blood vessels in the skin become visible. |
| • Infected wounds may take longer to heal. | |

The amount of sugar in your blood and urine may change or some of your hormones may be affected causing weight gain, menstrual irregularities and hair growth. These effects are very rare.

Some steroids are known to affect certain hormones. If your doctor thinks you need to be treated for longer periods of time, they may arrange for you to have hormone tests. If the ointment is affecting your hormones, your doctor may tell you to stop using it. Then your hormones should return to normal.

Children treated with topical steroids have rarely had high fluid pressure in their skulls. This has caused headaches and swelling.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE HAE LAN CREAM

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use Haelan Cream after the expiry date that is stated on the tube crimp and on the carton after Use Before. The expiry date refers to the last day of the month.

Medicines should not be disposed of via household waste. Please return any unused Haelan Cream to your pharmacist for safe disposal. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Haelan Cream contains

- The active substance is fludroxycortide, 0.0125% w/w
- The other ingredients are stearic acid, cetyl alcohol, polyoxyl 40 stearate, liquid paraffin, propylene glycol, sodium citrate, and citric acid.

What Haelan Cream looks like and contents of the pack

Haelan Cream is white and comes in a 60g aluminium tube.

Marketing Authorisation Holder:

Typharm Ltd, 14D Wendover Road, Rackheath Industrial Estate, Norwich, NR13 6LH.

Manufacturers

Pharmaserve Ltd, Clifton Technology Park, Wynne Avenue, Swinton, Manchester M27 8FF

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF

Date of Leaflet Preparation: April 2009.