

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**Haelan Cream 0.0125% w/w**

**Fludroxcortide**



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

## 1. WHAT HAELAN 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 and weeping. Haelan Cream can be used in adults and children.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE HAELAN CREAM

### Do not use Haelan Cream

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

Do not use Haelan Cream if you are allergic to fludroxcortide or any of the other ingredients of this medicine (listed in section 6).

### Warnings and precautions

- Talk to your doctor or pharmacist before using 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.

### Children

- Do not use Haelan Cream on children's skin for more than five days and do not cover it up tightly.

### Other medicines and Haelan Cream

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

### Pregnancy and breast-feeding

Do not use Haelan Cream 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.

### Important information about some of the ingredients of Haelan Cream

#### Haelan Cream contains cetyl alcohol and propylene glycol

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 HAELAN CREAM

Always use this medicine 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. 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 medicine, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

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

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 cream 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.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE HAELAN CREAM

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

Do not store above 25°C.

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

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 protect the environment.

### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Haelan Cream contains

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

#### What Haelan Cream looks like and contents of the pack

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

#### Marketing Authorisation Holder and Manufacturer

##### 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.

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