PACKAGE LEAFLET: INFORMATION FOR THE USER

HAELAN TAPE

TYPHARM

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.

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1. WHAT HAELAN TAPE IS AND WHAT IT IS USED FOR

Haelan Tape is a thin plastic surgical tape. Each square centimetre contains 4 micrograms of the steroid fludroxycortide. The tape is used on difficult to treat skin conditions, especially when the skin is dry and scaly.

BEFORE YOU USE HAELAN TAPE 2

- Do not use Haelan Tape for
 - chicken pox
 - skin reactions to smallpox vaccination
 - · tuberculosis of the skin
 - · 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 atheletes foot

Do not use Haelan Tape if you are allergic (hypersensitive) to fludroxycortide or to surgical plastic tape.

Take special care with Haelan Tape:

If you have ever had an allergic reaction to Haelan Tape (an allergic reaction may include a rash, itching, swelling or breathing difficulties) tell your doctor.

· If you have a skin infection or think you have skin infection tell your doctor.

 If you are using the tape on your face, you should only use the tape for 5 davs.

•Do not use Haelan Tape on children's skin for more than five days and do not cover it up tightly. This is because children may absorb more steroid medicine into their bodies than adults. If this happened for a long time it might stop them from growing or developing properly.

· Follow your doctor's instructions.

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 Tape if you are pregnant, think you could be pregnant, are planning to become pregnant or are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW TO USE HAELAN TAPE

Always use Haelan Tape exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Usual doses

Check the label for how to use your medicine and how often to use it. Only put the tape on the parts of your skin your doctor wants to treat.

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

Haelan Tape is easy to use.

Please follow these instructions.

Cleaning the skin

Before you apply Haelan Tape, make sure the affected skin is clean and dry. If you need to shave the skin around the affected area, your doctor or nurse will tell you how to do it.

Haelan Tape is waterproof so, once it is in place, you can wash, bathe, shower or even swim. Its matt surface means that you can apply make-up over it.

Cutting the tape

You cannot tear Haelan Tape. Always cut it with clean scissors. Make sure that the piece you cut is big enough just to cover the affected area and about 0.5cm of unaffected skin all around. Your doctor will tell you which area to treat. Round off the corners of the patch to stop it curling or catching on your clothes.

Applying Haelan Tape

Once you have removed the paper backing, throw it away and apply the adhesive side of the clear tape to your skin. Take care the tape does







not stick to itself as you take off the paper.

The tape will stick better if you stroke the back of it gently from the middle outwards.

If you need to cover an area of skin which is longer than 7 cm, do not take all the paper backing off when you cut the tape. Peel back a bit at a time as you stick the tape onto your skin.

· Haelan Tape is flexible

If the affected area is likely to be moving constantly, for example, because it is on your hands, fingers, feet, knees or elbows, apply the tape while the skin is flexed. Segments can be cut from the tape to allow you to mould the tape into shape over the affected area. If you are applying it to the outer surface of a knee or elbow, stick it on while the joint is bent. Then you should be able to bend the joint without disturbing the dressing.

· 'Awkward' areas

You may need someone to help you put Haelan Tape on areas which are difficult to reach.

Your doctor will tell you how long to use the tape for, this is usually 12 hours per day but can be longer.

Do not use Haelan Tape for long periods of time without speaking to your doctor.

Do not cover the tape with other dressings or tightly fitting clothes.

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 tape is affecting your hormones, your doctor may tell you to stop using it. Then your hormones should return to normal

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

POSSIBLE SIDE EFFECTS 4.

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

A few patients may have one or more of the following side effects in the area where they apply Haelan Tape

- Burning, itching, irritated or dry skin.
- · Excessive hair growth.
- · Acne pimples.
- · Pale skin.
- · Limp, flabby or thin skin where the tape was.
- Inflammation at the bottom of skin hairs.
- · Red spots or lines on the skin.

· Dermatitis around the mouth or contact dermatitis.

· The amount of sugar in your blood and urine may change or your

hormones may be affected, causing weight gain, menstrual irregularities and hair growth. These effects are rare.

· Skin infections may get worse if they are not treated with an antibiotic or other medicine.

· Wounds may take longer to heal.

· 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 HAELAN TAPE

Keep out of the reach and sight of children.

Do not use Haelan Tape after the expiry date that is stated on the carton after EXP. The expiry date refers to the last day of the month.

Store in a dry place, below 25°C. If your doctor tells you to stop using Haelan Tape, take any remaining tape back to the pharmacist for safe disposal. Medicines should not be disposed of via household waste. These measures will help to protect the environment.

FURTHER INFORMATION 6.

What Haelan Tape contains

The active substance is fludroxycortide (4 micrograms/cm²).

- The other ingredient is Blenderm surgical tape coated with synthetic adhesive.

What Haelan Tape looks like and contents of the pack

Haelan Tape is a translucent, polythene adhesive film, 7.5cm wide, protected by a removable paper liner.

It is available as a 50cm or 200cm roll or as individually wrapped 10cm pieces in packs of 5, 10 or 20.

Marketing Authorisation Holder:

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

Manufacturer:

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