



Diphenhydramine Hydrochloride

Please read this leaflet carefully before using this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist..

This leaflet contains the following information.

- 1. What is Histergan Cream and what does it do?
- 2. What should I know before using Histergan Cream?
- 3. How do I use Histergan Cream?
- 4. Does Histergan Cream have any side effects?
- 5. How do I store Histergan Cream?
- 6. Further information.

1. What is Histergan Cream and what does it do?

Histergan Cream is intended for the relief of minor discomforts due to allergic conditions of the skin. Such conditions include rashes and itches, stings and insect bites. The active ingredient is diphenhydramine hydrochloride which is an antihistamine; it works by reducing the inflammatory response to histamine, which is an agent responsible for causing the pain associated with allergic responses.

2. What should I know before using Histergan Cream?

When shouldn't I use Histergan Cream?

Do not use Histergan Cream if you are allergic to any of the ingredients listed in **section 6** of this leaflet. Do not apply to eczema, or conditions where the skin is broken or producing any form of wet discharge. Do not use the cream at the same time as using other products that also contain diphenhydramine. Histergan Cream is not suitable for children under six years of age.

Information about some of the ingredients in this medicine:

This medicine contains propyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

What else should I be aware of before using Histergan Cream?

Keep away from the eyes, nose and mouth. Apply sparingly, avoiding prolonged or repeated applications especially to large areas. If burning or a rash develops or the condition does not improve seek medical advice immediately. You can remove the cream by washing with soap and water if required.

What should I do if I accidentally swallow or use too much Histergan Cream?

Accidental swallowing or excessive use may lead to drowsiness and sedation. If this occurs seek medical advice immediately and do not drive. When seeking medical advice you should, if possible, take the medicine and this leaflet with you provided it doesn't cause a delay.

Can I use Histergan Cream if I am pregnant or breastfeeding?

The cream is considered safe for use during pregnancy and when breastfeeding, however you should always consult with a healthcare professional before using any medicines at this time.

Is it safe to drive or operate machinery after using Histergan Cream?

This product is safe to use prior to driving or operating machinery.

Are there any foods or medicines that interact with Histergan Cream?

No interactions of concern are known for this product.

3. How do I use Histergan Cream?

Apply sparingly to the affected area.

Do not use more than twice daily or for longer than three days.

FOR EXTERNAL USE ONLY

Wash your hands after use unless they are being treated.

Histergan Cream is not suitable for children under six years of age.

What should I do if I miss a treatment with Histergan Cream?

If you have missed a treatment then you can use the cream immediately provided you do not apply it more than twice daily.

4. Does Histergan Cream have any side effects?

All medicines can cause side effects. Although not common the following side effects have been reported to the ingredients of Histergan Cream:

- Allergic reactions, e.g. skin rash and/or swelling at or near the site of application.
- The skin may become sensitive to sunlight.
- Very occasionally, eczema.

If you experience any severe side effects including eczema, or have a side effect which isn't listed, then discontinue use and seek the advice of your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or 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 at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How do I store Histergan Cream?

Do not use after the expiry date marked on the pack. Keep all medicines out of the reach and sight of children, preferably in a locked cupboard. Store below 25°C.

6. Further information.

What is in Histergan Cream?

The active ingredient is **diphenhydramine hydrochloride** 2.0% m/m. In addition Histergan Cream also contains the following non-active ingredients: propyl hydroxybenzoate, liquid paraffin, emulsifying wax and purified water.

How is Histergan Cream supplied?

Histergan Cream is supplied in packs of 25g.

Who is responsible for Histergan Cream?

The marketing authorisation holder is:

Norma Chemicals Ltd., 51-53 Stert Street, Abingdon, Oxfordshire, England OX14 3JF

The manufacturer is:

Fleet Laboratories Ltd., 94 Rickmansworth Road, Watford, Hertfordshire, England WD18 7JJ

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