

Patient Information Leaflet

HISTALIX SYRUP

Diphenhydramine Hydrochloride 14 mg / 5 ml

Ammonium Chloride 135 mg / 5 ml

Levomenthol 1.1 mg / 5 ml

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.
- ⊗ You must contact a doctor if your symptoms worsen or do not improve.
- ⊗ If any side effect becomes more serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. **What Histalix Syrup is and what does it do?**
2. **What should I know before using Histalix Syrup?**
3. **How do I use Histalix Syrup?**
4. **Does Histalix Syrup have any side effects?**
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1. What Histalix Syrup is and what does it do?

The name of your medicine is Histalix Syrup.

It is for the symptomatic relief of troublesome cough associated with upper respiratory tract congestion. It may also be used to aid restful sleep.

The syrup contains the active ingredients diphenhydramine hydrochloride, ammonium chloride and levomenthol. Diphenhydramine Hydrochloride is an antihistamine that is used to provide relief from the effects of an allergy. Ammonium chloride is an expectorant that helps loosen phlegm and catarrh. Levomenthol relieves the discomfort of congestion and also provides a cooling effect in mouth and throat.

2. What should I know before using Histalix Syrup?

You should not use this medicine if you:

- ⊗ Are sensitive to any of the ingredients (full list provided in Section 6).
- ⊗ Are taking or have taken monoamine oxidase inhibitors (MAOI) (a treatment for depression) within the previous 14 days.
- ⊗ Are under 12 years old.

Talk to your doctor or pharmacist before taking this medicine if you:

- ⊗ Suffer from glaucoma.
- ⊗ Have difficulty urinating.
- ⊗ Have a cough with a lot of mucus.
- ⊗ Suffer from an enlarged prostate.
- ⊗ Have asthma.
- ⊗ Have any disorder of the liver.

Is it safe to drive or operate machinery after taking Histalix Syrup?

May cause drowsiness. Do not drive or operate machinery.

Are there any foods or medicines that interact with Histalix Syrup?

- ⊗ Avoid alcoholic drink.
- ⊗ You should not take any other treatment for coughs or colds while taking Histalix Syrup.

Histalix Syrup may react with other medicines you are taking, talk to a pharmacist or doctor if you are taking:

- ⊗ Any other antihistamines (typically used to treat allergies).
- ⊗ Sedative drugs (used to provide a calming effect).
- ⊗ Anti-anxiety agents.
- ⊗ Any other medication with a depressant action.
- ⊗ Any other decongestant medication.
- ⊗ Ephedrine (used to treat nasal congestion, diabetic swelling and other conditions)
- ⊗ Mono Amine Oxidase Inhibitors (MAOIs) (a treatment for depression).

You should also be aware that:

- ⊗ Certain antibiotics may damage hearing and Histalix Syrup may mask this damage initially.
- ⊗ If you are having skin tests to test for allergies then Histalix Syrup may mask a positive result.

Can I use Histalix Syrup if I am pregnant or breastfeeding?

Do not take if pregnant or breast feeding.

Important Information about some of the ingredients of Histalix Syrup

In addition to the active ingredients, some of the other ingredients in Histalix Syrup may affect some individuals as follows:

- ⊗ Histalix Syrup contains 1.66g of Sucrose in 5ml. When taken according to the dosage recommendations each dose supplies up to 3.32g of sucrose and is unsuitable for people with certain metabolic disorders such as hereditary fructose intolerance.
- ⊗ Glycerin (also known as glycerol) is harmful in high doses. It can cause headache, stomach upset and diarrhoea.
- ⊗ Parahydroxybenzoates can cause skin rashes and rarely bronchospasm.
- ⊗ The colouring E124 (ponceau 4R) which can cause allergic type reactions such as asthma, most commonly in individuals also allergic to aspirin.

3. How do I use Histalix Syrup?

Do not exceed the stated dose below.

Not suitable for children under 12 years.

Dosage:

One to two 5ml spoonfuls to be taken every 4 hours.

To aid sleep take two 5ml spoonfuls at bedtime followed by two 5ml spoonfuls every 6 hours.

Do not take more than 4 doses (one dose = two 5ml spoonfuls) in 24 hours.

Can I take too much Histalix Syrup?

If you have taken an **overdose** of Histalix Syrup you should seek medical attention as soon as possible. When seeking medical advice you should, if possible, take the medicine and this leaflet with you provided it doesn't cause a delay.

What should I do if I miss a dose of Histalix Syrup?

If you have missed a dose then provided it is delayed by no more than an hour take your dose immediately, otherwise wait until your next dose is due.

Do not take a double dose.

4. Does Histalix Syrup have any side effects?

Like all medicines, as well as benefits, Histalix Syrup can cause side effects. The following side effects have been reported to the ingredients of Histalix Syrup:

Common Side Effects:

- ☹ Drowsiness
- ☹ Excitability
- ☹ Headache
- ☹ Poor co-ordination
- ☹ Difficulty urinating
- ☹ Dryness of the mouth
- ☹ Stomach upset
- ☹ Thickened mucus

Rare Side Effects:

- ☹ Low blood pressure
- ☹ Muscle spasms
- ☹ Dizziness
- ☹ Confusion
- ☹ Depression
- ☹ Disturbed sleep
- ☹ Tremor
- ☹ Convulsions
- ☹ Irregular heartbeat or palpitations
- ☹ Allergic reactions
- ☹ Liver problems

If you experience any unexpected side effects not mentioned above, or the side effect (as listed) is severe or persists for more than a few days, discontinue use of the medicine and consult your doctor.

If you suffer from spontaneous bruising or bleeding (possible signs of a blood disorder) discontinue treatment and seek immediate advice from your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, 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 Histalix Syrup?

Keep all medicines out of the reach and sight of children, preferably in a locked cupboard.

Store below 30°C.

Do not use after the expiry date marked on the pack.

6. Further information

What Histalix Syrup contains:

Each 5ml of syrup contains the active ingredients diphenhydramine hydrochloride 14 mg, ammonium chloride 135 mg and levomenthol 1.1 mg. In addition Histalix Syrup also contains the following non-active ingredients: sucrose, sodium saccharin, ponceau 4R (E124), propylene glycol, raspberry flavouring, preservatives (E218, E215, E216 and butyl hydroxybenzoate), sodium citrate, glycerin and water.

What Histalix Syrup looks like and the contents of the pack:

Histalix Syrup is a clear red to maroon coloured syrup supplied in packs of 150ml.

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The Marketing Authorisation holder is:

Wallace Manufacturing Chemists Limited,
51-53 Stert Street, Abingdon, Oxfordshire, OX14 3JF, UK.

Manufactured by:

Laleham Health and Beauty Limited, Greenhalgh, Preston, PR4 3JA, UK.

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