

Patient Information Leaflet

HISTALIX SYRUP

Diphenhydramine Hydrochloride 14.00mg / 5 ml
Ammonium Chloride 135.00 mg / 5 ml
Levomenthol 1.10 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?**
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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 provide soothing relief of cough symptoms during sleep.

The syrup contains the active ingredients diphenhydramine hydrochloride, ammonium chloride and menthol. Diphenhydramine Hydrochloride is an antihistamine that produces subjective relief of the effects of allergic stimuli. Ammonium chloride is an expectorant that helps loosen phlegm and catarrh. Menthol 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
- ⓘ Are taking or have taken monoamine oxidase inhibitors (MAOI) within the previous 14 days.

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

- ⓘ Suffer from glaucoma
- ⓘ Have any form of bowel obstruction
- ⓘ Have a peptic ulcer
- ⓘ Suffer from an enlarged prostate
- ⓘ Have asthma
- ⓘ Have high blood pressure
- ⓘ Have an over active thyroid
- ⓘ Have severe coronary artery disease
- ⓘ Have any disorders of the liver or kidneys.

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.
- ⓘ Sedative drugs.
- ⓘ Anti-anxiety agents.
- ⓘ Betahistine.
- ⓘ Ephedrine
- ⓘ Mono Amine Oxidase Inhibitors (MAOIs).

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 2 years.

Children should take no more than 4 doses in 24 hours.

Consult your pharmacist before use in children under 6 years.

Dosage:

Children 2 to 5 years: Half of One 5ml spoonful to be taken every 4 hours.

Children 6 to 12 years: One 5ml spoonful to be taken every 4 hours.

Adults and Elderly: One to Two 5ml spoonfuls to be taken every 4 hours.

To aid sleep the bedtime dose may be changed to:

Children 2 to 5 years: no change.

Children 6 to 12 years: One to two 5ml spoonfuls.

Adults and Elderly: Two to three 5ml spoonfuls.

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. Although not common the following side effects have been reported to the ingredients of Histalix Syrup:

- ⊛ Sleep disturbances and sedation.
- ⊛ Poor co-ordination.
- ⊛ Confusion (particularly in the elderly).
- ⊛ Allergic reactions.
- ⊛ Blurred vision.
- ⊛ Dryness of the mouth.
- ⊛ Heart Palpitations.
- ⊛ Difficulty in urinating
- ⊛ Thickened mucus.
- ⊛ Sensitivity to light.
- ⊛ Excitability (usually restricted to children).
- ⊛ Tremors.

If you suffer from spontaneous bruising or bleeding discontinue treatment and seek immediate advice from your doctor.

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.

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 25°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 supplied in packs of 150ml.

PL 00400/0007R

The Marketing Authorisation holder is:

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

Manufactured by:

Universal Products (Lytham) Manufacturing Limited,
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