Patient Information Leaflet

UNICOUGH ORAL SOLUTION

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 Unicough Oral Solution is and what does it do?
- 2. What should I know before using Unicough Oral Solution?
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1. What Unicough Oral Solution is and what does it do?

The name of your medicine is Unicough Oral Solution.

It is for the symptomatic relief of common coughs (such as dry and/or tickly, or troublesome cough) associated with upper respiratory tract congestion. It may also be used to aid restful sleep.

The product contains the active ingredients diphenhydramine hydrochloride, ammonium chloride and levomenthol.

Diphenhydramine hydrochloride is an antihistamine that possesses antitussive, antihistaminic, and anticholinergic properties and suppresses the urge to cough. It also dries up secretions in the nose and chest. Experiments have shown that the antitussive effect is discrete from its sedative effect. Taken at night will assist sleeping.

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.

Unicough oral solution is a thick demulcent, which in the buccal cavity and throat forms a soothing film over the mucous membrane. This brings it into contact with the sensitive nerve endings of the throat lining.

2. What should I know before using Unicough Oral Solution?

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 Unicough Oral Solution? May cause drowsiness. Do not drive or operate machinery.

Are there any foods or medicines that interact with Unicough Oral Solution?

- Avoid alcoholic drink.
- You should not take any other treatment for coughs or colds while taking Unicough Oral Solution.

Unicough Oral Solution 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 Unicough Oral Solution may mask this damage initially.
- If you are having skin tests to test for allergies then Unicough Oral Solution may mask a positive result.

Can I use Unicough Oral Solution if I am pregnant or breastfeeding?

Do not take if pregnant or breast feeding.

Important Information about some of the ingredients of Unicough Oral Solution

In addition to the active ingredients, some of the other ingredients in Unicough Oral Solution may affect some individuals as follows:

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Contains 1.7 g sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus.
- Parahydroxybenzoates may cause allergic reactions (possible delayed). .

3. How to use Unicough Oral Solution?

Do not exceed the stated dose. Not suitable for children under 12 years.

Shake well before use.

Dosage:

One to two 5ml spoonfuls of 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 Unicough Oral Solution?

If you have taken an **overdose** of Unicough Oral Solution 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 Unicough Oral Solution?

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 Unicough Oral Solution have any side effects?

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

Common Side Effects:

- Drowsiness
- Excitability
- Headache
- Poor co-ordination
- Difficulty urinating
- Dryness of the mouth

Rare Side Effects:

- Low blood pressure
- Muscle spasms
- Dizziness
- Confusion
- Depression
 - Disturbed Sleep

- Stomach upset
- Thickened mucus
- Blurred Vision

- Tremor
- Convulsions
- Irregular heartbeat or palpitations
- Allergic reactions
- Liver problems
- Blood disorders (see below)

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 or pharmacist. This includes possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 Unicough Oral Solution?

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 bottle.

6. Further information

What Unicough Oral Solution contains:

Each 5ml of oral solution contains the active ingredients diphenhydramine hydrochloride 14 mg, ammonium chloride 135 mg and levomenthol 1.1 mg.

In addition Unicough Oral Solution also contains the following non-active ingredients: Sucrose, Cocoa flavour, Glycerol, Propylene Glycol, Sodium Citrate, Preservatives (E218, E215, E216 and Butyl hydroxybenzoate), and Water.

What Unicough Oral Solution looks like and the contents of the pack:

Unicough Oral Solution is a smooth brown oral solution supplied in packs of 150ml or 300ml, with a red plastic measuring spoon.

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The Marketing Authorisation holder is:

infirst HEALTHCARE Limited Central Point, 45 Beech Street, London, EC2Y 8AD, UK.

Manufactured by:

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This leaflet was revised in September 2015.

If you have any queries or comments about your medicine or any other infirst Healthcare Ltd products, ring our customer line 0808 281 0143.