

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Histalix Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains :-

Diphenhydramine HCl	14.00 mg
Ammonium Chloride	135.00 mg
Levomenthol	1.10 mg

Excipient(s) with known effect:

Sucrose	1.66g/5ml
Ponceau 4R (E124)	0.33mg/5ml
Propylene Glycol	0.5ml/5ml
Nipastat	6mg/5ml
Glycerin (also known as Glycerol)	0.75ml/5ml

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution

Appearance: clear red to maroon coloured syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the oral symptomatic relief of troublesome cough associated with upper respiratory tract congestion and aids restful sleep

4.2 Posology and method of administration

Posology

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

To aid sleep the patient may start with two 5ml spoonfuls at bedtime followed by two 5ml spoonfuls every 6 hours.

Not suitable for children under 12 years.

Do not take more than 4 doses (1 dose = two 5ml spoonfuls) in 24 hours.

Do not exceed the stated dose.

Method of Administration

Oral

4.3 Contraindications

- Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.
- Children below 12 years of age
- Patients on monoamine oxidase inhibitor therapy within previous 14 days (see section 4.5)

4.4 Special warnings and precautions for use

Do not combine with other treatments for coughs and colds.

Histalix syrup should be used with caution in patients with the following conditions: prostatic hypertrophy, urinary retention, susceptibility to 'closed angle' glaucoma and hepatic disease.

Histalix Syrup may cause drowsiness.

Seek medical advice when suffering from chronic or persistent cough and when also suffering from asthma, and acute asthmatic attack or where cough is accompanied by excessive secretions

Keep out of the reach and sight of children.

Ponceau 4R may cause allergic reactions.

Glycerol may cause headache, stomach upset and diarrhoea.

Parahydroxybenzoates may cause allergic reactions (possible delayed)

This medicine contains 0.5ml Propylene Glycol per 5ml dose. If you are pregnant or suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine

Sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

- Additive CNS depressant effects with alcohol and other CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and anti-psychotics.
- Additive anti-muscarinic effects with other drugs of similar properties such as atropine and some anti-depressants.
- Not to be taken in patients taking monoamine oxidase inhibitors (MAOIs) or within 14 of stopping treatment as there is a risk of serotonin syndrome.
- Diphenhydramine can inhibit the oxidative metabolism of some drugs.
- Diphenhydramine may enhance the effects of ephedrine.
- Diphenhydramine may mask the response of the skin to allergenic skin tests and also the ototoxic symptoms associated with certain antibiotics.

4.6 Fertility, pregnancy and lactation

Pregnancy

In view of the potential risks versus small benefits, it is recommended that Histalix syrup should not be used during pregnancy particularly as the safety of Histalix in human pregnancy is not established.

Lactation

In view of the potential risks versus small benefits, it is recommended that Histalix syrup should not be used during lactation particularly as the safety of Histalix in human pregnancy is not established

4.7 Effects on ability to drive and use machines

Histalix syrup may cause drowsiness. Do not drive or operate machinery. Avoid alcoholic drink.

4.8 Undesirable effects

The overall percentage of treated patients expected to experience adverse reactions is unknown.

Common side effects include:

CNS effects such as nervous drowsiness (usually diminishes within a few days), paradoxical stimulation, nervous headache, nervous psychomotor impairment.

Anti-muscarinic effects such as urinary retention, dry mouth, blurred vision, gastrointestinal disturbances and thickened respiratory tract secretions.

Rare side effects include:

Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

Organ system Class	Common ADRs, >1/100, < 1/10	Uncommon ADRs, >1/1,000, <1/100	Rare ADRs >1/10,000, <1/1000
Blood Lymphatic System Disorder			Blood Disorders NOS
Cardiac Disorder			Palpitation, arrhythmia
Eye Disorders	Blurred vision		
Gastrointestinal Disorder	Dry mouth, gastrointestinal disturbance		
General Disorder	Paradoxical drug reaction		
Hepatobiliary Disorder			Liver Disorder
Immune System Disorders			Hypersensitivity
Nervous System Disorders	Psychomotor skills impairment, drowsiness, headache		Tremor, convulsions, extrapyramidal disorder, dizziness

Organ system Class	Common ADRs, >1/100, < 1/10	Uncommon ADRs, >1/1,000, <1/100	Rare ADRs >1/10,000, <1/1000
Psychiatric Disorders			Confusion, depression, sleep disturbances
Renal and Urinary Disorder	Urinary retention		
Respiratory Disorder	Increased upper airway secretion		
Vascular Disorders			Hypertension

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Symptoms of overdosage include those due to diphenhydramine or levomenthol (drowsiness, dizziness, ataxia, anti-cholinergic effects, pyrexia, headaches, convulsions, hallucinations, excitement and respiratory depression).

Treatment consists of gastric lavage and aspiration. Administration of activated charcoal may help. Other symptomatic and supportive measures should be provided.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use

ATC Code: R06AA52

Diphenhydramine May suppress cough centre (mechanism unknown). Subjective relief of effects of allergic stimuli. Taken at night will assist sleeping

Ammonium Chloride "Traditional" Expectorant. May induce mild acidosis which is counteracted by the excipient sodium citrate.

Levomenthol Subjective relief of upper respiratory congestion. Whilst retained as a thick syrup in buccal cavity and throat provides cooling effect.

5.2 Pharmacokinetic properties

Diphenhydramine

Is a histamine receptor antagonist, Main site of metabolic transformation is the liver, Oral availability - 50%, Plasma bound - 80%, Half life - 4 hours

Ammonium Chloride

Effectively absorbed from GI tract.

Ammonium Ion converted to urea by the liver.

Acid ion released gives mild metabolic acidosis.

Levomenthol

After absorption Levomenthol is excreted in the urine and bile as a glucuronide

5 PHARMACOLOGICAL PROPERTIES

5.3 Preclinical safety data

There are no preclinical data of relevance, within are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose, Sodium Saccharin, Ponceau 4R (E124), Propylene Glycol, Raspberry Flavour, Nipastat (methylparahydroxybenzoate E218, ethylparahydroxybenzoate E215, propylparahydroxybenzoate E216, butylparahydroxybenzoate), Sodium Citrate, Glycerin, Purified Water.

6 PHARMACEUTICAL PARTICULARS

6.2 Incompatibilities

See Section 4.5

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

150ml Glass bottle.

Cap White PP28 TE CR with EPE/PE/AL/PET Wad

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 0400/0007R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd June 1972, 1999

10 DATE OF REVISION OF THE TEXT

22/05/2025