

# UNIHIST SYRUP

Brompheniramine maleate 4 mg ; Phenylephrine hydrochloride 10 mg

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## What UNIHIST is used for

For the symptomatic relief of nasal congestion due to cough and cold and allergic conditions, mainly rhinitis [inflammation of the nasal mucous membranes].

## How UNIHIST works

Brompheniramine/ phenylephrine is an antihistamine and decongestant combination. The antihistamine works by blocking the action of histamine, which helps reduce symptoms such as watery eyes and sneezing. The decongestant promotes sinus and nasal drainage, which relieves congestion and pressure.

## Before you use UNIHIST

### -When you must not use it

- ⊗ If you are allergic (hypersensitive) to Brompheniramine or Phenylephrine or to any other drugs of similar chemical structure.
- ⊗ If you are allergic (hypersensitive) to any of the other ingredients of UNIHIST.
- ⊗ If you are pregnant and breast-feeding
  - ⇒ UNIHIST should be used only if the potential benefit to the patient outweighs the possible risk to the fetus.
  - ⇒ UNIHIST should be used only if the potential benefit to the patient outweighs the possible risk to the infant.

Do not use this medicine if any of the above applies to you. If you are not sure, get advice from your doctor or pharmacist before taking UNIHIST.

### -Before you start to use it

Inform your doctor in cases of:

- Liver or kidney problems
- Epilepsy
- Severe hyperthyroidism (pathologically excessive production of thyroid hormones)
- Severe ischemic heart disease
- Diabetes mellitus or prostatic hyperplasia [nonmalignant (noncancerous) enlargement of the prostate gland, a common occurrence in older men] should also avoid Phenylephrine.
- Pregnant and breast feeding mothers
- Had symptoms of anaphylaxis (hypersensitivity induced by preliminary exposure to a substance and usually producing a contraction of smooth muscle and a dilatation of blood vessels) with other "azole" drugs in the past.
- Children below 2 years of age – exercise caution and follow the instruction of doctor or pharmacist when giving to children between 2 to 6 years of age.

In such cases, please consult your doctor before taking the medicine.

### -Taking other medicines

Please inform your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that you buy without prescription and herbal medicines.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Central nervous system (CNS) depressants such as sedatives, opioid analgesics and hypnotics, may cause an increase sedative effect.
- Monoamine oxidase (MAO) inhibitors and Tricyclic antidepressants (TCAs) may prolong and intensify the anticholinergic and CNS depressive effects.
- Sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants may cause an increase in blood pressure and additive effects

- Methyldopa and  $\beta$ - blockers may cause an increase in blood pressure.

## How to use UNIHIST

### -How much to use

Oral

Adults:

5 mL (1 teaspoonful) every 4 to 6 hours

Children:

6 – 12 years: 2.5 mL (1/2 teaspoon) every 4 to 6 hours

### -When to use it

Do not take UNIHIST few hours before bedtime because it may possibly cause insomnia.

### -How long to use it

Continue taking UNIHIST for as long as your doctor recommends.

### -If you forget to use it

If you miss a dose, take the next dose as soon as you remember, provided that you do not take more than the recommended dose in 24 hours. If it is almost time for your next dose, do not take the dose that you missed. Do not take a double dose.

### -If you use too much (Overdose)

Symptoms: Nervousness, tremor, insomnia, agitation, irritability, abdominal pain, severe headache, nausea, and vomiting.

In case you accidentally take too much and experienced the above mentioned overdosage symptoms, contact your doctor immediately or contact your nearest hospital.

## While you are using it

### -Things you must do

- ⊗ Take your medicine exactly as your doctor has told you.
- ⊗ Tell all the doctors, dentists and pharmacists treating you that you are taking UNIHIST.

⊗ Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

- ⊗ Alcohol drinking
- ⊗ Do not stop taking the medicine unless advised by your doctor.
- ⊗ Do not take any new medicines without consulting your doctor.
- ⊗ Do not give UNIHIST to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

⊗ Activities requiring mental alertness:

Do not drive a car or operate potentially dangerous tools or machines. UNIHIST may cause drowsiness or dizziness.

**Side effects**

As with all drugs, UNIHIST is likely to have undesirable effects:

- Sedation
- Impaired performance (impaired driving performance, poor work performance, incoordination, reduced motor skills, and impaired information processing); Performance may be impaired in the absence of sedation and may persist the morning after a night-time dose.
- Anxiety
- Hallucinations
- Appetite stimulation
- Muscle dyskinesia [An impairment in the ability to control movements, characterized by spasmodic or repetitive motions or lack of coordination]
- Activation of epileptogenic foci [the area of the cerebral cortex responsible for causing epileptic seizures]
- Dryness of the eyes, mouth and nose
- Blurred vision
- Urinary hesitancy and retention
- Constipation
- Tachycardia [a rapid heart rate, especially one above 100 beats per minute in an adult]

Others: Children and elderly are more likely to experience adverse

effects such as skin rashes and urinary retention than other age groups.

If any of the side effects happens, or if you notice any undesirable effects which have not been mentioned here, discontinue using this medication and consult your doctor / pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling *Tel: 03-78835550*, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

**Storage and Disposal of UNIHIST**

-Storage

Store at temperature of not more than 30°C

-Disposal

Shelf – life: Two (2) years  
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

-What it looks like

Clear, purple syrup with grape flavor

-Ingredients

Active ingredients:  
Brompheniramine maleate;  
Phenylephrine hydrochloride

Inactive ingredients:  
Sodium benzoate, Saccharin sodium, Citric acid anhydrous, Grape essence, Carmoisine, Brilliant blue FCF, Sucrose, Edetate disodium, Sodium citrate dihydrate, Glycerin, Sorbitol solution 70% and Purified water

-MAL Number:

MAL08061561A

**Manufacturer**

UNISON LABORATORIES CO., LTD.  
39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000 Thailand

**Product Registration Holder**

MEDISPEC (M) SDN.BHD  
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**Date of Revision**

20/05/2014