

## ALLERSOOTHE

Allersoothe Tablets (Promethazine hydrochloride)

Allersoothe Elixir (Promethazine hydrochloride)

Promethazine hydrochloride 5mg/5ml Elixir Sugar Free

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Allersoothe.

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Allersoothe against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your pharmacist or doctor.**

**Keep this leaflet with the medicine.**

You may need to read it again.

#### What Allersoothe is used for

Allersoothe is an antihistamine used to treat a number of conditions:

- allergies - allergic contact dermatitis, hives, hayfever, bites and stings
- respiratory symptoms due to allergies - runny nose
- nausea and vomiting - motion sickness
- assists in the management of the symptoms of chicken pox and measles by acting as a sedative
- for short-term use for sedation on the advice of a pharmacist or doctor - do not use for more than 7-10 days

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances that the body is allergic to.

Your pharmacist or doctor may have recommended Allersoothe for another reason.

**Ask your pharmacist or doctor if you have any questions about this medicine.**

**Allersoothe should not be used in children under 2 years of age, due to the potential for fatal respiratory depression.**

**This medicine may affect your ability to drive a car or operate machinery.**

#### Before you take it

##### *When you must not take it*

**Do not take Allersoothe if you have an allergy to:**

- any medicine containing promethazine hydrochloride
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have or have had any of the following medical conditions:

- Glaucoma (high pressure in the eyes)

- Stomach or duodenal ulcer, or other stomach problems
- Prostate problems
- Bladder problems

**Do not take Allersoothe if you are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression.**

**Do not take Allersoothe if you have jaundice.**

**Do not take this medicine if you are receiving or have received high doses of other CNS depressant medications (for example, drugs that are used to treat anxiety and sleep disorders).**

**Any person who is unconscious or in a coma must not be treated with Allersoothe.**

**Do not give Allersoothe to newborn or premature babies.**

**Do not use for children under two years of age, due to the potential for fatal respiratory depression.**

**Do not take Allersoothe if you are pregnant or plan to become pregnant.**

It may affect your developing baby if you take it during pregnancy. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

**Do not take Allersoothe if you are breastfeeding or plan to breastfeed.**

It passes into the breast milk and there is a possibility that the baby may be affected.

**Do not take Allersoothe after the expiry date (EXP) printed on the pack.**

If you take this medicine after the expiry date has passed, it may not work as well.

**Do not take Allersoothe if the packaging is torn or shows signs of tampering.**

##### *Before you start to take it*

**Tell your pharmacist or doctor if you have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes

**Tell your pharmacist or doctor if you have or have had any medical conditions, especially the following:**

- kidney or liver disease
- epilepsy
- cardiovascular disease
- blood pressure problems
- breathing problems

**Tell your doctor if you plan to have surgery.**

**Tell your pharmacist or doctor if you take sedatives.**

**Tell your pharmacist or doctor if you are pregnant or intend to become pregnant.**

Allersoothe is not recommended for use during pregnancy. If there is a need to consider Allersoothe during your pregnancy, your pharmacist or doctor will discuss with you the benefits and risks of taking it.

**Do not take Allersoothe if you are breastfeeding or plan to breastfeed.**

It passes into the breast milk and there is a possibility that the baby may be affected.

#### *Taking other medicines*

**Tell your pharmacist or doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and Allersoothe may interfere with each other. Allersoothe may increase the sedative effect of some drugs. These include:

- medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants
- medicines used to help you sleep or relax (sedatives and hypnotics)
- opioid analgesics, medicines used to treat pain
- other antihistamines
- alcohol

These medicines may be affected by Allersoothe or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your pharmacist and doctor will have more information on medicines to be careful with or avoid while taking this medicine.

#### How to take it

##### *How much to take*

**Follow all directions given to you by your pharmacist or doctor carefully.**

They may differ from the information contained in this leaflet.

Allersoothe 25mg tablets are recommended for adults and children 6-12 years only on the advice of a pharmacist or doctor. Allersoothe tablets are not recommended for use in children under 6 years of age - Allersoothe elixir is recommended for children 2-6 years of age. Allersoothe tablets or elixir should not be used in children under 2 years of age.

##### *Allergic Disorder*

Adults and children over 12 years: One to three 25mg tablets as a single dose at night, or one to two 10mg tablets, two to three times daily.

Children 6-12 years: One 10mg or one 25mg tablet, or 10 to 25mL of the elixir as a single dose at night, or one 10mg tablet, or 10mL of the elixir, two to three times daily.

Children 2-5 years: 5-15mL of elixir as a single dose at night, or 5mL of elixir, two to three times daily.

##### *Sedation*

For short term use on the advice of a pharmacist or doctor.

Adults and children over 12 years: One to three 25mg tablets as a single dose at night.

Children 6-12 years: One 10mg or one 25mg tablet, or 10 to 25mL of the elixir, as a single dose at night.

Children 2-5 years: 5-15mL of elixir as a single dose at night.

##### *Travel Sickness*

Adults and children over 12 years: One 25mg tablet.

Children 6-12 years: One 10mg tablet or 10mL of the elixir.

Children 2-5 years: 5mL of elixir.

To be taken the night before travel and repeated after 6 to 8 hours on the following day if required.

### *Nausea and Vomiting*

Adults and children over 12 years: One 25mg tablet every 4 to 6 hours to a maximum daily dose of four 25mg tablets.

Children 6-12 years: One 10mg tablet or 10mL of the elixir, every 4 to 6 hours to a maximum daily dose of two 10mg tablets or 20mL of the elixir.

Children 2-5 years: 5mL of elixir every 4 to 6 hours to a maximum daily dose of 15mL.

**If you do not understand the instructions on the carton or the label, ask your pharmacist or doctor for help.**

**Do not take more than the recommended dose.**

### *Use in the Elderly*

**If you are over 65 years of age, talk to your pharmacist or doctor about how much to take.**

Elderly patients are more likely to have side effects from taking these medicines.

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## How to take it

### **Tablets**

Swallow Allersoothe tablets whole with a full glass of water.

### **Elixir**

Measure out the amount of elixir to be taken with a measuring device.

### *How long to take it*

**Allersoothe should not usually be taken for more than 10 days in a row. If your symptoms persist, see your pharmacist or doctor for advice.**

### *If you forget to take it*

**If you are taking Allersoothe for an allergic disorder and you forget to take your bedtime dose, you may need to take your dose in two or three smaller doses during the following day.** Check with your pharmacist or doctor.

**If you are taking Allersoothe for travel sickness or nausea and vomiting, take your dose as soon as you remember.**

**If you are taking Allersoothe for sedation, take your dose as soon as you remember.**

Be careful because you may still be affected in the morning.

**Do not take a double dose to make up for the dose that you missed.**

This may be harmful.

**If you are not sure what to do, ask your pharmacist or doctor.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### *If you take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand, call 0800 764 766) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Allersoothe.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

**If you take too much Allersoothe, you may experience:**

### **Adults**

- drowsiness

- convulsions and/or tremors
- difficulty breathing
- unconsciousness
- acute anxiety
- hallucinations

### **Children**

- over - excitement
- shaky and unsteady movements
- convulsions and/or tremors
- hallucinations
- difficulty breathing
- unconsciousness
- high fever

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## While you are taking it

### *Things you must do*

**If you have eczema or a tendency to rheumatism, Allersoothe may cause your skin to be more sensitive to the sun. You should protect your skin from exposure to bright sunlight.**

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Allersoothe.**

**If you are about to be started on any new medicine, tell your pharmacist or doctor that you are taking Allersoothe.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.**

**If you become pregnant while you are taking this medicine, stop taking it and tell your doctor immediately.**

**Talk to your pharmacist or doctor if your symptoms do not improve.**

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

### *Things you must not do*

**Do not give Allersoothe to anyone else, even if they have the same condition as you.**

**Do not take Allersoothe to treat any other complaints unless your pharmacist or doctor tells you to.**

**Do not drink alcohol while taking Allersoothe.** The sedation effects of alcohol may be increased.

**Do not take more than the recommended dose unless your pharmacist or doctor tells you to.**

### *Things to be careful of*

**Allersoothe is a known sedative and may cause drowsiness in some people.**

Make sure you know how you react to Allersoothe before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy. If this occurs do not drive or operate machinery.

**If you have a single dose at bedtime, you may still be affected in the morning.**

**Avoid alcohol.**

**Children and the elderly are especially sensitive to the effects of antihistamines.**

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## Side effects

Allersoothe may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Allersoothe.**

**Tell your pharmacist or doctor if you notice any of the following and they worry you:**

- dry mouth, nose & throat
- stomach upset
- loss of appetite
- nausea or vomiting
- diarrhoea or constipation
- tiredness or sleepiness
- restlessness
- dizziness
- blurred vision

The above list includes the more common side effects of Allersoothe.

They are usually mild.

**Tell your pharmacist or doctor immediately if you notice any of the following:**

- fever
- difficulty breathing
- irregular heart beat
- jaundice - yellow tinge to skin or eyes
- tremors or convulsions
- tinnitus - buzzing, hissing, ringing or other persistent noise in the ears
- seizures (fits)
- hallucinations
- nervousness and irritability
- anxiety
- twitching or jerking muscles

The above list includes serious side effects that may require medical attention. These side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rashes

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your pharmacist or doctor if you notice anything that is making you feel unwell.**

Other side effects not listed above may occur in some patients.

**Do not be alarmed by the lists of possible side effects.**

You may not experience any of them.

**Ask your pharmacist or doctor if you have any questions.**

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## After taking Allersoothe

### *Storage*

**Keep your medicine in the pack until it is time to take it.**

If you take your medicine out of the pack it will not keep as well.

**Keep your tablets in a cool dry place where the temperature stays below 30°C**

**Keep your elixir in a cool dry place, protected from light, where the temperature stays below 30°C**

**Do not store Allersoothe or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on window sills.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

**If your pharmacist or doctor tells you to stop taking Allersoothe or if it has passed the expiry date, ask your pharmacist what to do with any left over.**

### *What it looks like*

Allersoothe Tablets are available in two strengths:

- 10mg - Light blue coloured, circular biconvex film coated tablets, plain on both the sides
- 25mg - Light blue coloured, circular biconvex film coated tablets plain on both sides

Both tablet strengths are available in blister packs of 50 tablets

Allersoothe Elixir is sugar free, alcohol free, banana and vanilla flavoured syrupy liquid.

Allersoothe elixir is available in a 100mL bottle.

### *Ingredients*

#### **Allersoothe Elixir**

##### **Active ingredient:**

- promethazine hydrochloride 5 mg / 5 mL.

##### **Inactive ingredients:**

- sodium benzoate
- propyl gallate
- citric acid anhydrous
- vanillin
- banana flavour
- glycerol
- disodium edetate
- sodium citrate
- propylene glycol
- sunset yellow FCF
- quinoline yellow
- hydroxyethylcellulose
- purified water.

#### **Allersoothe tablets**

##### **Active ingredient:**

- 10 mg promethazine hydrochloride per tablet
- 25 mg promethazine hydrochloride per tablet

##### **Inactive ingredients: (for both 10mg and 25mg tablets)**

- lactose
- hypromellose
- magnesium stearate
- methyl cellulose
- macrogol 6000
- purified talc
- titanium dioxide
- brilliant blue FCF aluminium lake.

### *Sponsor*

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