

FENEZINE

Active ingredient(s): *Promethazine hydrochloride* (PRO-meth-ar-zine HIGH-dro (h)-CLOR-ride)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fenezine. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fenezine.**

Where to find information in this leaflet:

- [1. Why am I using Fenezine?](#)
- [2. What should I know before I use Fenezine?](#)
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- [4. How do I use Fenezine?](#)
- [5. What should I know while using Fenezine?](#)
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1. Why am I using Fenezine?

Fenezine contains the active ingredient promethazine hydrochloride.

Fenezine 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 Fenezine for another reason.

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

2. What should I know before I use Fenezine?

Warnings

Fenezine must not be used in children under 6 years of age, due to the potential for fatal respiratory depression, psychiatric and CNS events.

Do not use Fenezine if:

- you are allergic to promethazine hydrochloride, medicines of similar properties or belonging to the specific family of chemicals called phenothiazines, other phenothiazines, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. 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

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

- **the packaging is torn or show signs of tampering.**

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

Do not give Fenezine to newborn or premature babies.

Check with your doctor or pharmacist if you:

- have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes
- have any other medical conditions, especially the following:
 - kidney or liver disease
 - parkinson's disease
 - underactive thyroid gland (hypothyroidism)
 - tumour growing in adrenal glands (pheochromocytoma)
 - autoimmune disorder (myasthenia gravis)
 - epilepsy
 - cardiovascular disease/cardiac failure
 - blood pressure problems
 - low white blood cell count (agranulocytosis)
 - bladder problems
 - breathing problems
 - glaucoma - an eye condition
 - prostate problems
 - stomach ulcer or blockage
- develop a fever or an infection to confirm if laboratory tests are required to check your blood count
- plan to have surgery
- take sedatives
- take any medicines for any other condition
- have any personal or family history of heart disease
- have an irregular heartbeat

If you experience an allergic reaction, seek medical help right away.

Caution must be exercised when using Fenezine due to the risk of sedation.

If you experience fever, sore throat or any other infection, you should inform your doctor or pharmacist immediately and undergo a complete blood count. Treatment should be discontinued if any marked changes are observed in the blood count.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are a woman of childbearing age and not using effective contraception. Check with your doctor or pharmacist if you are pregnant, might become pregnant or think you may be pregnant.

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

It may affect your developing baby if you take it during pregnancy. If there is a need to consider Fenezine during your pregnancy, Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

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

Use in Children

- **Do not give Fenezine to newborn or premature babies.**
- **Fenezine must not be used in children under 6 years of age, due to the potential for fatal respiratory depression, psychiatric and CNS events.**
- **Because of the risk of choking, the tablets should be avoided in children who have difficulty swallowing tablets.**

Use in Elderly

- If you are over 65 years of age, talk to you pharmacist or doctor about how much to take.
- Elderly patients are more likely to have side effects from taking these medicines.

3. What if I am taking other medicines?

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

Some medicines may interfere with Fenezine and affect how it works.

Fenezine may increase the sedative effect of some medicines. 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 and alcohol containing medicines
- medicines for the treatment of irregular heartbeats (antiarrhythmics)
- medicines that help with your mood (antidepressants)
- medicines used to help with mental illness (antipsychotics)
- medicines to treat infections (antimicrobials)
- medicines used to treat nausea and vomiting like metoclopramide
- medicines used to relieve muscle spasm like carisoprodol and cyclobenzaprine
- medicines used for the treatment of epilepsy or seizures
- medicines used to treat acid indigestion such as magnesium, aluminium and calcium salts, oxides and hydroxides
- medicines used to smooth muscle contractions in the gastrointestinal tract (antispasmodics)

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Fenezine.

4. How do I use Fenezine?

How much to take

- Follow the instructions provided with the medicine. If you do not understand the instructions on the carton or the label, ask your pharmacist or doctor for help.
- Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.
- Use this drug only as recommended.
- Do not exceed the recommended dosage. There have been case reports of promethazine abuse.
- Fenezine tablets are recommended for adults and children over 6 years of age.
- **It is recommended that the lowest effective dose of Fenezine be used in children 6 years of age or older.**

Allergic Disorder

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

- Children 6-12 years: one to two 10 mg tablets as single dose at night or one 10 mg tablet two to three times daily.

Sedation

- For short term use on the advice of a pharmacist or doctor.
- Adults and children 12 years and over: One to three 25 mg tablets as a single dose at night.
- Children 6-12 years: One to two 10 mg tablets as a single dose at night.

Travel Sickness

- Adults and children 12 years and over: One 25 mg tablet.
- Children 6-12 years: One 10 mg tablet.
- To be taken the night before travel and repeated after 6-8 hours on the following day if required.

Nausea and Vomiting

- Adults and children 12 years and over: One 25 mg tablet every 4 to 6 hours to a maximum daily dose of four 25 mg tablets.
- Children 6-12 years: One 10 mg tablet every 4 to 6 hours to a maximum daily dose of two 10 mg tablets.

How to take Fenezine

- Swallow Fenezine tablets whole with a full glass of water.

How to long to take Fenezine

- Fenezine 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 use Fenezine

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

If you are taking Fenezine 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 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 use too much Fenezine (overdose)

If you think that you have used too much Fenezine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much Fenezine, you may experience:

Adults

- drowsiness
- convulsions and/or tremors
- difficulty breathing
- unconsciousness
- acute anxiety
- hallucinations
- heart palpitations, chest pain and/or rapid pulse
- dizziness
- nausea
- cold sweats

Children

- over – excitement
- shaky and unsteady movements
- convulsions and/or tremors
- hallucinations
- difficulty breathing
- unconsciousness
- high fever
- heart palpitations, chest pain and/or rapid pulse
- dizziness
- nausea
- cold sweats
- memory and thinking problems; difficulty with learning new things, concentrating, or making decisions

5. What should I know while using Fenezine?

Things you should do

- Fenezine may cause your skin to be more sensitive to the sun. You should protect your skin from exposure to bright sunlight.
- If you are about to be started on any new medicine, tell your pharmacist or doctor that you are taking Fenezine.
- 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.

Remind any doctor, dentist or pharmacist you visit that you are using Fenezine.

Things you should not do

- Do not give Fenezine to anyone else, even if they have

the same condition as you.

- Do not take Fenezine to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Things to be careful of

- Fenezine is a known sedative and may cause drowsiness in some people.
- If you have a single dose at bedtime, you may still be affected in the morning.
- Children and the elderly are especially sensitive to the effects of antihistamines

Neuroleptic malignant syndrome

A very serious and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Stop treatment and call your doctor right away if you have high fever, muscle cramps or stiffness, dizziness, very bad headache, fast heartbeat, confusion, agitation, hallucinations, or are sweating a lot.

Driving or using machines

Fenezine can cause drowsiness, dizziness and blurred vision. Make sure you know how you react to Fenezine before you drive a car, operate machinery, or do anything else that could be dangerous if you experience drowsiness, dizziness and blurred vision. If this occurs do not drive or operate machinery.

Be careful before you drive or use any machines or tools until you know how Fenezine affects you.

Fenezine may affect your ability to drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or experience blurred vision. If this occurs do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Do not drink alcohol while taking Fenezine.

The sedation effects of alcohol may be increased.

Looking after your medicine

- 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.
- Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place below 30°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General <ul style="list-style-type: none">• dry mouth, nose & throat Nervous system-related <ul style="list-style-type: none">• tiredness or sleepiness• headache• involuntary muscle movements (dystonia) Mental <ul style="list-style-type: none">• nightmares in children• restlessness• confusion• anxiety• aggression• hallucination Gastrointestinal or Gut <ul style="list-style-type: none">• stomach upset• loss of appetite• nausea or vomiting• diarrhoea or constipation Eye disorders <ul style="list-style-type: none">• blurred vision Respiratory <ul style="list-style-type: none">• congested nose Skin related <ul style="list-style-type: none">• increase sensitivity of the skin to the sun	Speak to your doctor if you have any of these less serious side effects and they worry you. These are mild side effects of the medicine and are short-lived.

Serious side effects

Serious side effects	What to do
General <ul style="list-style-type: none">• fever• excessive sweating• dizziness	Call your doctor straight away if you notice any

<ul style="list-style-type: none"> • nausea • cold sweats • low blood pressure • shortness of breath <p>Urinary</p> <ul style="list-style-type: none"> • difficulty passing urine <p>Heart</p> <ul style="list-style-type: none"> • irregular heart beat • very fast or forceful heartbeats (palpitations) • chest pain • rapid pulse <p>Blood and Lymphatic System Disorders</p> <ul style="list-style-type: none"> • eosinophilia which is an increase in the number of eosinophils (a type of white blood cells) found in the blood test. • Thrombocytopenia which is a decrease in the number of platelets (cells in the blood that help with clotting) found in a blood test, which can lead to bleeding and bruising (thrombocytopenic purpura). <p>Allergy related</p> <ul style="list-style-type: none"> • difficulty breathing <p>Liver related</p> <ul style="list-style-type: none"> • jaundice – yellow tinge to skin or eyes <p>Nervous system related</p> <ul style="list-style-type: none"> • tremors or convulsions • tinnitus – buzzing, hissing, ringing or other persistent noise in the ears • confusion • twitching or jerking muscles • dizziness, lightheadedness • severe headache • muscle cramps or stiffness • psychomotor hyperactivity <p>Central nervous system related</p> <ul style="list-style-type: none"> • anxiety • seizures (fits) • hallucinations • agitation • nervousness and irritability 	<p>of these serious side effects.</p> <p>These are serious side effects that may require medical attention. Serious side effects are rare.</p>
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<p>or other parts of the body/ severe allergic reaction where adrenaline is required for treatment (anaphylaxis)</p> <ul style="list-style-type: none"> • skin rashes 	<p>Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These side effects are very rare.</p>
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Fenezine contains

Active ingredient (main ingredient)	10 mg or 25mg of promethazine hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • microcrystalline cellulose • magnesium stearate • anhydrous calcium hydrogen phosphate • hypromellose • macrogol • opaspray blue M-1-4210A
Potential allergens	Contains no lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What Fenezine looks like

Fenezine 10mg tablets – round, pale blue to blue, film coated tablets, plain on both sides (Aust R 351892).

Fenezine 25mg tablets – round, pale blue to blue, film coated tablets, plain on both sides (Aust R 351891).

Pack size of 50 tablets.

Who distributes Fenezine

Sandoz Pty Ltd
100 Pacific Highway

Very serious side effects	What to do
<p>Allergy related</p> <ul style="list-style-type: none"> • wheezing or difficulty breathing • swelling of the face, lips, tongue 	<p>Call your doctor straight away, or go straight to the</p>

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