

Sandoz Fenezal®

Promethazine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sandoz Fenezal. 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 Sandoz Fenezal 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 Sandoz Fenezal is used for

Sandoz Fenezal 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 Sandoz Fenezal for another reason.

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

Sandoz Fenezal 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 Sandoz Fenezal

When you must not take it

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

Do not take Sandoz Fenezal 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 Sandoz Fenezal.

Do not give Sandoz Fenezal to newborn or premature babies.

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

This product is not recommended for children under 6 years of age. A liquid alternative should be considered in children 2-6 years of age.

Do not take Sandoz Fenezal 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 Sandoz Fenezal 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 Sandoz Fenezal 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 Sandoz Fenezal 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
- bladder problems
- breathing problems
- glaucoma - an eye condition
- prostate problems
- stomach ulcer or blockage.

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.

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

Do not take Sandoz Fenezal 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 Sandoz Fenezal may interfere with each other. Sandoz Fenezal 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 Sandoz Fenezal 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 Sandoz Fenezal

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

They may differ from the information contained in this leaflet.

How much to take

Sandoz Fenezal tablets are recommended for adults and children over 12 years of age. This product is not suitable for children aged 6-12 years unless on pharmacist or medical advice.

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 to two 10mg tablets as a single dose at night, or one 10mg tablet two to three times daily.

Sedation

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

Adults:

One to three 25mg tablets as a single dose at night.

Children 6-12 years:

One to two 10mg tablets as a single dose at night.

Travel Sickness

Adults:

One 25mg tablet.

Children 6-12 years:

One 10mg tablet.

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

Nausea and Vomiting

Adults:

One 25mg tablet every 4 to 6 hours to a maximum daily dose of four 25mg tablets.

Children 6-12 years:

One 10mg tablet every 4 to 6 hours to a maximum daily dose of two 10mg tablets.

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. Do not take for longer than 10 days.

Use this drug only as recommended. Do not exceed the recommended dose. There have been case reports of promethazine abuse.

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.

How to take it

Swallow Sandoz Fenezal tablets whole with a full glass of water.

How long to take it

Sandoz Fenezal 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 Sandoz Fenezal 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 Sandoz Fenezal for travel sickness or nausea and vomiting, take your dose as soon as you remember.

If you are taking Sandoz Fenezal 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) 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 Sandoz Fenezal. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Sandoz Fenezal, 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.

While you are using Sandoz Fenezal

Things you must do

If you have eczema or a tendency to rheumatism, Sandoz Fenezal 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 Sandoz Fenezal.

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

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 Sandoz Fenezal to anyone else, even if they have the same condition as you.

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

Do not drink alcohol while taking Sandoz Fenezal. 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

Sandoz Fenezal is a known sedative and may cause drowsiness in some people.

Make sure you know how you react to Sandoz Fenezal 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.

A very serious and sometime 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.

Avoid alcohol.

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

Side effects

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

Sandoz Fenezal 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.

Ask your pharmacist or doctor if you have any questions.

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 Sandoz Fenezal. 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
- agitation
- anxiety
- twitching or jerking muscles.
- muscle cramps or stiffness
- dizziness
- severe headache
- confusion
- excessive sweating

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.

Other side effects not listed above may occur in some patients. Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

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

You may not experience any of them.

After using Sandoz Fenezal

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.

Do not store Sandoz Fenezal 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 Sandoz Fenezal or if it has passed the expiry date, ask your pharmacist what to do with any left over.

Product Description

What it looks like

Sandoz Fenezal Tablets are available in two strengths:

- 10mg - round and pale blue tablets, with 'PN 10' embossed on one side.
- 25mg - round and pale blue tablets, with 'PN 25' embossed on one side.

Both tablet strengths are available in blister packs of 50 tablets.

Ingredients

Sandoz Fenezal Tablets

Active Ingredient

- 10mg tablets - 10mg of promethazine hydrochloride per tablet.
- 25mg tablets - 25mg of promethazine hydrochloride per tablet.

Inactive Ingredients

The 10mg and 25mg tablets also contain:

- lactose
- starch maize
- povidone
- magnesium stearate
- hypromellose
- macrogol 200
- blue opaspray.

Supplier

Sandoz Pty Ltd
 ABN 60 075 449 553
 54 Waterloo Road
 Macquarie Park
 NSW 2113,
 Australia
 Tel: 1800 634 500

Australian Registration Numbers:

Sandoz Fenezal 10mg tablets
 AUST R 134531
 Sandoz Fenezal 25mg tablets
 AUST R 134532

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