

Betahistine Sandoz

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Betahistine Sandoz?

Betahistine Sandoz contains 16 mg of the active ingredient betahistine dihydrochloride. Betahistine Sandoz is used to treat an inner ear disorder called Meniere's syndrome, which may cause ringing in the ears, hearing loss or balance problems and sometimes nausea, vomiting and headache.

For more information, see Section [1. Why am I using Betahistine Sandoz?](#) in the full CMI.

2. What should I know before I use Betahistine Sandoz?

Do not use if you have ever had an allergic reaction to Betahistine Sandoz or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Betahistine Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Betahistine Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Betahistine Sandoz?

- The usual adult starting dose is half to one 16 mg tablet taken three times a day. Your doctor may however prescribe a different dose. The maximum recommended daily dosage is 48 mg.
- Swallow Betahistine Sandoz with a glass of water following food, and at about the same time each day.

More instructions can be found in Section [4. How do I use Betahistine Sandoz?](#) in the full CMI.

5. What should I know while using Betahistine Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Betahistine Sandoz.• Tell your doctor if you have or have had a peptic ulcer, suffer from asthma, have a history of allergic skin conditions or tumours of the adrenal gland, have or have had any other medical conditions including pregnancy or breastfeeding, or have any allergies to any other medicines or substances.
Things you should not do	<ul style="list-style-type: none">• Do not give Betahistine Sandoz to anyone else, even if they have the same condition as you.• Do not take Betahistine Sandoz to treat any other complaints unless your doctor tells you to.• Do not stop taking Betahistine Sandoz, or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• If you have dizziness from your condition or this medication, do not drive or use machines until you are sure that the dizziness has eased.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool, dry place where the temperature stays below 25°C.• Keep your tablets in the pack until it is time to take them.

For more information, see Section [5. What should I know while using Betahistine Sandoz?](#) in the full CMI.

6. Are there any side effects?

Common side effects include skin irritations, stomach upsets, dizziness, fast heart-beat, headache, difficulty sleeping, tiredness, nausea, vomiting, bloating, swollen stomach and diarrhoea.

Serious side effects include skin reactions, difficulty breathing, convulsions, hallucinations, confusion, allergic reaction, low blood pressure and slow heart-beat.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Betahistine Sandoz

Active ingredient: betahistine dihydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Betahistine Sandoz. **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 Betahistine Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Betahistine Sandoz?](#)
- [2. What should I know before I use Betahistine Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Betahistine Sandoz?](#)
- [5. What should I know while using Betahistine Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Betahistine Sandoz?

Betahistine Sandoz contains the active ingredient betahistine dihydrochloride.

Betahistine Sandoz is used to treat a disorder of the working of your inner ear. This disorder may include one or more of the following symptoms, in one or both ears:

- Ringing in the ears (tinnitus)
- Loss of clear hearing
- Problems with balance (vertigo)

These symptoms may also be associated with nausea, vomiting and headache. Often these symptoms together are referred to as Ménière's Syndrome.

Betahistine Sandoz tablets contain the active ingredient betahistine dihydrochloride, which work by improving the blood flow of the inner ear and restoring it to normal. It also acts on the nerve endings in the inner ear to normalize the way in which the nerves respond to outside influences.

Your doctor may have prescribed Betahistine Sandoz for another reason. Ask your doctor if you have any questions about why Betahistine Sandoz has been prescribed for you.

There is no evidence that Betahistine Sandoz is addictive.

2. What should I know before I use Betahistine Sandoz?

Warnings

Do not use Betahistine Sandoz if:

- you are pregnant or intend to become pregnant. Betahistine Sandoz may affect your developing baby if taken during pregnancy.

- you are breast-feeding or plan to breast-feed. Betahistine Sandoz may pass into breast milk and therefore there is possibility that the breast-fed baby may be affected.
- you are allergic to betahistine dihydrochloride or any of the ingredients listed at the end of this leaflet. Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.
- you have a rare abnormality of the adrenal gland known as phaeochromocytoma.
- you have or have had a peptic ulcer.

Do not give Betahistine Sandoz to children under 18 years of age.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

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 if you are pregnant or intend to become pregnant.

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

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 and Betahistine Sandoz may interfere with each other.

These include:

- any antihistamine medications, which are used to treat allergies and allergic reactions
- monoamine oxidase inhibitors (MAOIs) (e.g. some antidepressants, selegiline)

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Betahistine Sandoz.

4. How do I use Betahistine Sandoz?

How much to take

- The usual adult starting dose is half to one 16mg Betahistine Sandoz tablet, taken three times a day. However your doctor may prescribe a different dose depending on the severity of your condition.
- The maximum recommended daily dosage is 48 mg.
- Swallow Betahistine Sandoz with a glass of water.
- Follow the instructions provided and use Betahistine Sandoz until your doctor tells you to stop.
- If you follow your doctor's instructions Betahistine Sandoz should start working within a few days, although in some cases it may take a few weeks. The length of time that you should take Betahistine Sandoz tablets varies from patient to patient.

When to take Betahistine Sandoz

- Take Betahistine Sandoz at about the same time each day. Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.
- Take Betahistine Sandoz during or immediately after a meal, at about the same time each day. If you take Betahistine Sandoz on an empty stomach, it may cause stomach upsets.

If you forget to use Betahistine Sandoz

Betahistine Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time,

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much Betahistine Sandoz

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

The most common symptom of overdosing is nausea.

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.

5. What should I know while using Betahistine Sandoz?

Things you should do

Tell your doctor if you have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Tell your doctor if:

- you have or have had a peptic ulcer
- you suffer from asthma
- you have a history of allergic skin conditions or if you have or have had any other medical conditions.

Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of using Betahistine Sandoz during pregnancy. If you become pregnant while taking Betahistine Sandoz, tell your doctor immediately.

Tell your doctor if you are breastfeeding or plan to breast-feed. Your doctor will discuss the possible risks and benefits of using Betahistine Sandoz during breastfeeding.

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

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

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

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

- Do not give Betahistine Sandoz to anyone else, even if they have the same condition as you.
- Do not take Betahistine Sandoz to treat any other complaints unless your doctor tells you to.
- Do not stop taking Betahistine Sandoz, or lower the dosage without checking with your doctor.

Driving or using machines

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

Your condition or Betahistine Sandoz may cause dizziness in some people.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- Keep your tablets in a cool, dry place where the temperature stays below 25°C.

Store it in a cool dry place 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.

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
<ul style="list-style-type: none"> • skin irritations • stomach upsets • dizziness • fast heart-beat • headache • difficulty sleeping (insomnia) • tiredness • nausea, vomiting, bloating, or swollen stomach • diarrhoea 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • skin reactions • difficulty breathing • convulsions • hallucinations • confusion • allergic reaction • low blood pressure, slow heart beat 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

Betahistine Sandoz tablets contain 16 mg of the active ingredient betahistine dihydrochloride.

What Betahistine Sandoz contains

Active ingredient (main ingredient)	betahistine dihydrochloride
Other ingredients (inactive ingredients)	lactose monohydrate maize starch microcrystalline cellulose citric acid povidone crospovidone hydrogenated vegetable oil.
Potential allergens	lactose monohydrate

Contains sugars as lactose.

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

What Betahistine Sandoz looks like

Betahistine Sandoz tablets are white and flat with beveled edges. They have a breakline on one side. Available in packs of 25 tablets. (AUST R 253732)

Who distributes Betahistine Sandoz

Sandoz Pty Ltd
54 Waterloo Road
Macquarie Park, NSW, 2113
Australia
Tel: 1800 726 369

This leaflet was prepared in March 2021.