

Betahistine Sandoz

Betahistine dihydrochloride tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Betahistine Sandoz tablets. It does not contain all the available information. It does not take the place of talking to your doctor and pharmacist.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Betahistine Sandoz tablets against the benefits this medicine is expected to have for you.

Keep this leaflet with the medicine. You may need to read it again.

What Betahistine Sandoz is used for

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.

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

Before you take Betahistine Sandoz

When you must not take it

Do not take 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.

Do not take Betahistine Sandoz after the expiry date (EXP) printed on the pack.

Do not take Betahistine Sandoz if the packaging is torn or shows signs of tampering, or if the tablets do not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Betahistine Sandoz, talk to your doctor or pharmacist.

Before you start to take it

You must tell your doctor if you have allergies to:

- any other medicines
- 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.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor will discuss the possible risks and benefits of using Betahistine Sandoz during breastfeeding.

If you have not told your doctor about any of the above, tell them before you start taking Betahistine Sandoz.*Taking other medicines***Tell your doctor if you are taking any other medicines, including medicines 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)

These medicines may be affected by Betahistine Sandoz or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

How take Betahistine Sandoz

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

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.*How much to take*

The usual adult starting dose is half to one 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.

How to take it

Swallow Betahistine Sandoz with a glass of water.

When to take it

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.

How long to take it

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. Some people respond rapidly to treatment and others may take some time. Please be patient with your treatment and take your tablets regularly. Do not stop taking your medicine unless your doctor tells you to - even if you feel better.

If you forget to take your tablets

If it is almost time for your next dose, skip the dose you missed and

take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

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

If you take too much (overdose)

Immediately contact your doctor or pharmacist or the Poisons Information Centre (In Australia, call 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Betahistine Sandoz. Do this even if there are no signs of discomfort or poisoning.

The most common symptom of overdosing is nausea.

While you are taking Betahistine Sandoz

Things you must do

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

If you become pregnant while taking Betahistine Sandoz, tell your doctor immediately.

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 must 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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Betahistine Sandoz. 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 doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list.

You may not experience any of them.

If you get any side effects, do not stop taking Betahistine Sandoz without first talking to your doctor.

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

- skin irritations
- stomach upsets
- dizziness
- fast heart beat
- headache
- difficulty sleeping (insomnia)
- tiredness

- nausea, vomiting, bloating, or swollen stomach
- diarrhoea

These side effects are usually mild and often short-lived. Some symptoms may also be present as part of your disorder. Stomach upsets can be overcome by taking Betahistine Sandoz during meals.

Tell your doctor as soon as possible if you notice any of the following:

- skin reactions
- difficulty breathing
- convulsions
- hallucinations
- confusion
- allergic reaction
- low blood pressure, slow heart beat

These may be serious side effects. You may need medical attention. Serious side effects are very rare.

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

After using Betahistine Sandoz

Storage

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool, dry place where the temperature stays below 25°C. Do not store Betahistine Sandoz or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep Betahistine Sandoz tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the

ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Betahistine Sandoz, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What the tablets look like

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

Ingredients

Active ingredient:

Betahistine Sandoz 16 mg tablet - 16 mg betahistine dihydrochloride.

Inactive ingredients:

- lactose monohydrate
- maize starch
- microcrystalline cellulose
- citric acid
- povidone
- crospovidone
- hydrogenated vegetable oil.

Contains sugars as lactose.

Supplier/ Distributor

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

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16 mg tablet: AUST R 253732
(blisters)