

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Betahistine Mylan.

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

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What Betahistine Mylan is used for

Betahistine Mylan is used to treat a disorder 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 Meniere's Syndrome.

Betahistine Mylan tablets contain the active ingredient betahistine dihydrochloride.

Betahistine Mylan works 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 normalise the way in which the nerves respond to outside influences.

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is not addictive.

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

Before you take Betahistine Mylan

When you must not take it

Do not take Betahistine Mylan if you have an allergy to:

- **any medicine containing betahistine dihydrochloride**
- **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.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

The active ingredient in Betahistine Mylan may pass into breast milk and therefore there is a possibility your baby may be affected.

Do not give Betahistine Mylan to a child under the age of 18 years.

Do not take this medicine if you a rare abnormality of the adrenal gland known as pheochromocytoma.

Do not take this medicine if you have or have had a peptic ulcer.

Do not take it after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

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

Before you start to take it

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

Tell your doctor if you have or have had any of the following medical conditions:

- a peptic ulcer
- asthma
- a history of allergic skin conditions

Tell your doctor if you are pregnant, intend to become pregnant, or are breastfeeding

Your doctor can discuss the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you take Betahistine Mylan.

Taking other medicines

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

Some medicines and Betahistine Mylan may interfere with each other. These include:

- any anti-histamine medications, which are used to treat allergies and allergic reactions

These medicines may be affected by Betahistine Mylan, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Betahistine Mylan.

How to take Betahistine Mylan

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

They may differ from the information contained in this leaflet.

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.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take Betahistine Mylan at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take Betahistine Mylan during or immediately after a meal.

If you take Betahistine Mylan on an empty stomach, it may cause stomach upsets.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you follow your doctor's instructions Betahistine Mylan 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 Mylan tablets varies from patient to patient. Some patients respond rapidly to treatment and others may take some time. Please be patient with your treatment and take your tablets regularly.

If you forget to take it

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 getting an unwanted side effect.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Betahistine Mylan. Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include nausea.

While you are using Betahistine Mylan

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Betahistine Mylan.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

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

Do not stop taking Betahistine Mylan, or change 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 Mylan.

It helps most people, but it may have unwanted side effects in a few people. All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side-effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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)

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Stomach upsets can be overcome by taking Betahistine Mylan during meals.

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

- skin reactions
- difficulty breathing

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

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

After using Betahistine Mylan

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool, dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

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 doctor or pharmacist tells you to stop taking this medicine, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

BETAHISTINE MYLAN tablets 16 mg are white, round, scored, with "267" on either side of the score.

Betahistine Mylan 16 mg tablets are available in packs of 25 tablets.

Ingredients

Betahistine Mylan contains 16 mg of betahistine dihydrochloride as the active ingredient:

It also contains

- colloidal anhydrous silica
- microcrystalline cellulose
- mannitol
- citric acid monohydrate
- purified talc

Betahistine Mylan does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Supplier

Betahistine Mylan is made in France.

Betahistine Mylan is supplied in Australia by:

Mylan Health Pty Ltd
Level 1, 30 The Bond,
30-34 Hickson Road
Millers Point, NSW 2000
Ph: 1800 314 527

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Australian Registration Number(s)

16 mg tablet: AUST R 286806

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