

## APO-Betahistine Tablets

*Betahistine dihydrochloride*

### Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

#### What is in this leaflet

This leaflet answers some common questions about betahistine. 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 has weighed the risks of you using 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 want to read it again.

#### What this medicine is used for

Betahistine is used to treat Meniere's Syndrome, a disorder of the inner ear.

Meniere's Syndrome 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.

#### How it works

Betahistine 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 this medicine has been prescribed for you.**

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

There is not enough information to recommend using this medicine in children less than 18 years of age.

#### Before you take this medicine

##### When you must not take it

**Do not take this medicine if you have an allergy to:**

- betahistine dihydrochloride
- 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, throat or other parts of the body
- skin rash, itching or hives on the skin

**Do not take this medicine if you have phaeochromocytoma, a rare abnormality of the adrenal gland.**

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

**Do not take this medicine if you are pregnant.**

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

**Do not take this medicine if you are breastfeeding.**

Betahistine may pass into human breast milk and there is a possibility your baby may be affected.

This medicine is not addictive.

**Do not give this medicine to a child under the age of 18 years.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

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

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

##### Before you start to take it

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

**Tell your doctor if you have or have had any medical conditions, especially asthma, peptic ulcer and a history of allergic skin conditions.**

**Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.**

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

##### Taking other medicines

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

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

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

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other medicines not listed above may also interact with betahistine.

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

#### How to take this medicine

**Follow all directions given to you by your doctor carefully.**

They may differ to 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

Your doctor will tell you how much of this medicine you should take.

This will depend on your condition and whether you are taking any other medicines.

The usual adult starting dose is 8 to 16 mg (half to one tablet) taken three times a day.

The maximum recommended daily dose is 48 mg.

However, your doctor may prescribe a different dose depending on the severity of your condition.

Follow the instructions provided and continue taking this medicine as long as your doctor tells you.

##### How to take it

Swallow the tablet whole with a full glass of water.

##### When to take it

**Take this medicine at about the same time each day.**

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

The tablets may be taken with or without food. If gastrointestinal upset occurs, it is recommended that the tablets be taken with meals.

##### How long to take it for

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

This medicine 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 this medicine varies from patient to patient. Please be patient with your treatment and take your medicine regularly.

##### If you forget to take it

**If it is almost time to take 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 missed doses.**

This may increase the chance of you experiencing side effects.

**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 to help you remember.**

##### If you take too much (overdose)

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

#### While you are taking this medicine

##### Things you must do

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

**Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.**

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

**If you become pregnant while taking this medicine, 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 this medicine to anyone else, even if they have the same condition as you.**

**Do not take your medicine to treat any other complaint unless your doctor tells you to.**

**Do not stop taking your medicine or change the dosage without first checking with your doctor.**

**Driving or using machines**

This medicine is indicated for Meniere's syndrome with symptoms of vertigo, hearing loss and tinnitus which can negatively affect the ability to drive and use machines.

This medicine is shown to have no or negligible effects to affect the ability to drive.

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## Side effects

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

This medicine helps most people with Meniere's Syndrome, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, 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 the following lists of 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 (can be overcome by taking this medicine during meals)
- 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.

**If any of the following happen, stop taking this medicine and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin (symptoms of an allergic reaction)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may occur in some patients.

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## Storage and disposal

### *Storage*

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

If you take your medicine out of the pack it may not keep well.

**Keep your medicine in a cool dry place where the temperature stays below 25°C.**

**Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

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

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## Product description

### *What it looks like*

#### **16mg Tablet:**

White or almost white, round, flat bevelled edged tablets embossed B16 on one side and scored on the other side.

Available in blister packs (Clear PVC/PVDC/Aluminium silver foil) of 25 tablets. AUST R 217105.

### *Ingredients*

Each tablet contains 16 mg of Betahistine as the active ingredient.

It also contains the following:

- povidone
- microcrystalline cellulose
- lactose monohydrate
- colloidal anhydrous silica
- crospovidone
- stearic acid

This medicine contains sugars as lactose.

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

### *Sponsor*

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