

## APO-Betahistine

Contains the active ingredient betahistine dihydrochloride

### Consumer Medicine Information

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

#### What is in this leaflet

##### Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

##### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

#### What this medicine is used for

The name of your medicine is APO-Betahistine Tablet. It contains the active ingredient betahistine dihydrochloride.

It 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 and vomiting.

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.

Keep this leaflet with your medicine. You may want to read it again.

##### 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.

There is no evidence that this medicine is addictive.

##### Use in children

This medicine should not be used 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 or have had any of the following:**
  - pheochromocytoma, a rare abnormality of the adrenal gland
  - peptic ulcer.
- **You are pregnant.**  
Betahistine may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding.**  
Betahistine may pass into human breast milk.
- **You are hypersensitive to, or have had an allergic reaction to, betahistine dihydrochloride or any of the ingredients listed at the end of this leaflet.**  
Symptoms of an allergic reaction may include: cough, 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; fainting; or hay fever-like symptoms.  
**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

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

##### Before you start to take it

##### Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially asthma.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with betahistine. These include:

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

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with betahistine.

#### How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

##### 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 16mg taken three times a day.

The maximum total daily dose recommended is 48mg.

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

##### How to take it

Swallow the tablet with a full glass of water.

##### When to take it

Take this medicine at 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.

If you follow your doctor's instructions 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. Some patients respond rapidly to treatment and others may take some time. 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 missed dose and take your next dose at the usual time. 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 have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

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

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.**

**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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

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

### *Things you must not do*

#### **Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

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### **Possible side effects**

Tell your doctor as soon as possible if you do not feel well while you are taking betahistine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

#### **Tell your doctor if you notice any of the following:**

- skin irritations
- stomach upsets
- dizziness
- fast heart beat
- headache.

#### **Tell your doctor as soon as possible if you notice any of the following.**

These may be serious side effects and you may need medical attention:

- skin reaction
- difficulty breathing.

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

### *Allergic reactions*

**If you think you are having an allergic reaction to betahistine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

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### **Storage and disposal**

#### *Storage*

**Keep your medicine in its original packaging until it is time to take it.**

If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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### **Product description**

#### *What APO-Betahistine Tablet 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.

#### *Ingredients*

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

It also contains the following inactive ingredients:

- Povidone
- Microcrystalline cellulose
- Lactose
- Colloidal anhydrous silica
- Crospovidone
- Stearic acid

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

#### *Australian Registration Numbers*

APO-Betahistine 16mg Tablet:  
AUST R 217105.

#### *Sponsor*

**Apotex Pty Ltd**  
16 Giffnock Avenue  
Macquarie Park NSW 2113

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