

APO-BETAHISTINE

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 APO-BETAHISTINE?

APO-BETAHISTINE contains the active ingredient betahistine dihydrochloride. APO-BETAHISTINE 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 and 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.

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

2. What should I know before I use APO-BETAHISTINE?

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

Do not take this medicine if you have peptic ulcer or a rare abnormality of the adrenal gland known as phaeochromocytoma.

Talk to your doctor if you have any other medical conditions (e.g. peptic ulcer, asthma or a history of skin 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 APO-BETAHISTINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-BETAHISTINE 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 APO-BETAHISTINE?

- The usual adult starting dose is half to one tablet taken three times a day.
- Take APO-BETAHISTINE at about the same time each day during or immediately after a meal.

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

5. What should I know while using APO-BETAHISTINE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-BETAHISTINE.• If you are going to have surgery, tell the surgeon that you are taking this medicine.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking APO-BETAHISTINE, or change the dosage, without checking with your doctor.• Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.
Driving or using machines	<ul style="list-style-type: none">• APO-BETAHISTINE 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.• APO-BETAHISTINE is shown to have no or negligible effects to affect the ability to drive.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the pack until it is time to take them.• Keep the medicine in a cool, dry place where the temperature stays below 25°C.• Keep it where children cannot reach it.

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

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following and they worry you: skin irritations, stomach upsets, dizziness, fast heartbeat, headache and difficulty sleeping (insomnia). Stomach upsets can be overcome by taking APO-BETAHISTINE during meals.

Tell your doctor as soon as possible if you notice any skin reactions or difficulty breathing.

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.

APO-BETAHISTINE

Active ingredient(s): *betahistine dihydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-BETAHISTINE. **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 APO-BETAHISTINE.**

Where to find information in this leaflet:

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

1. Why am I using APO-BETAHISTINE?

APO-BETAHISTINE contains the active ingredient **betahistine dihydrochloride**.

APO-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.

APO-BETAHISTINE 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.

2. What should I know before I use APO-BETAHISTINE?

Warnings

Do not use APO-BETAHISTINE if:

- **you are allergic to betahistine dihydrochloride, or any of the ingredients listed at the end of this leaflet.**
- Always check the ingredients to make sure you can use this medicine.
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 give APO-BETAHISTINE to a child under the age of 18 years.**

- **Do not take APO-BETAHISTINE if you have a rare abnormality of the adrenal gland known as phaeochromocytoma.**
- **Do not take APO-BETAHISTINE if you have or have had a peptic ulcer.**
Do not take APO-BETAHISTINE if the packaging is damaged or shows signs of tampering.

Check with your doctor if you:

- **have or have had any of the following medical conditions:**
 - peptic ulcer
 - asthma
 - a history of allergic skin conditions

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.

Do not take this medicine if you are pregnant.

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

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

Do not breastfeed if you are taking this medicine.

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

This medicine is not addictive.

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 APO-BETAHISTINE 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 APO-BETAHISTINE, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines.

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

4. How do I use APO-BETAHISTINE?

How much to take / use

- 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.
- Follow the instructions provided and continue taking APO-BETAHISTINE as long as the doctor tells you.
- If you follow your doctor's instructions, APO-BETAHISTINE 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 APO-BETAHISTINE 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.

When to take APO-BETAHISTINE

- Take APO-BETAHISTINE 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 APO-BETAHISTINE during or immediately after a meal.
- If you take APO-BETAHISTINE on an empty stomach, it may cause stomach upsets.

How to take APO-BETAHISTINE

- Swallow the tablet with a full glass of water.

If you forget to take APO-BETAHISTINE

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 you missed.

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

If you use too much APO-BETAHISTINE

If you think that you have used too much APO-BETAHISTINE, you may need urgent medical attention.

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.

Symptoms of an overdose may include nausea.

5. What should I know while using APO-BETAHISTINE?

Things you should do

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

Call your doctor straight away if you:

- if you become pregnant while you are taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using APO-BETAHISTINE.

Things you should not do

- Do not stop taking this medicine suddenly, or change the dosage, without checking with your doctor.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-BETAHISTINE affects you.

[medicine name] may cause dizziness in some people [or insert relevant information, as appropriate].

Drinking alcohol

APO-BETAHISTINE 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.

APO-BETAHISTINE is shown to have no or negligible effects to affect the ability to drive.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place below 25°C 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?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-BETAHISTINE.

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.

More common side effects

More common side effects	What to do
<ul style="list-style-type: none">• skin irritations• stomach upsets (can be overcome by taking APO-BETAHISTINE during meals)• dizziness• fast heartbeat• headache• difficulty sleeping (insomnia)	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are usually mild and short-lived.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• skin reactions• difficulty breathing	<p>Call your doctor as soon as possible if you notice these side effects.</p> <p>They may require medical attention. Serious side effects are rare.</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.

What APO-BETAHISTINE contains

Active ingredient (main ingredient)	betahistine dihydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• colloidal anhydrous silica• crospovidone• lactose monohydrate• microcrystalline cellulose• povidone• stearic acid
Potential allergens	lactose

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

What APO-BETAHISTINE 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 of 25 tablets (AUST R 217105)

Who distributes APO-BETAHISTINE

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne, Victoria 3121
Australia
www.arrotex.com.au

This leaflet was prepared in August 2024.