

## BETAHISTINE GH

(betahistine dihydrochloride) uncoated tablet

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some of the common questions people ask about Betahistine GH. It does not contain all the information that is known about Betahistine GH. 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 taking Betahistine GH 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 GH is used for

Betahistine GH 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 your 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 GH tablets contain the active ingredient betahistine dihydrochloride. 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.

Your doctor will have explained why you are being treated with Betahistine GH and told you what dose to take.

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

They may differ from the information contained in this leaflet.

This medicine is only available with a doctor's prescription. Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Betahistine GH is not addictive.

#### Before you take Betahistine GH

##### When you must not take it

**Do not use Betahistine GH 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 GH may pass into breast milk and therefore there is a possibility your baby may be affected.

**Do not give Betahistine GH to children under 18 years of age.**

**Do not take this medicine if you have 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 this medicine after the use by (expiry) date printed on the pack or if the packaging is damaged or shows signs of tampering.**

If it is 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 with you the risks and benefits involved.

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

*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 GH 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 GH, 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 GH.

#### How to take Betahistine GH

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

##### 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 GH 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 GH during or immediately after a meal.

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

##### How long to take it

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

If you follow your doctor's instructions, Betahistine GH 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 GH 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 (13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Betahistine GH. Do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose may include nausea.

#### While you are taking Betahistine GH

##### Things you must do

If you are about to start taking any other medicine, tell your doctor and pharmacist that you are taking Betahistine GH.

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 give Betahistine GH to anyone else, even if they have the same condition as you.**

**Do not use Betahistine GH tablets to treat any other complaints unless your doctor or pharmacist tells you to.**

**Do not stop taking Betahistine GH, or change the dosage, without checking with your doctor.**

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## Side effects

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

Betahistine GH 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, 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 GH 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. You 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.**

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## After taking Betahistine GH

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### *Storage*

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

If you take Betahistine GH out of the blister pack it will not keep well.

**Keep it in a cool dry place, protected from light and moisture where the temperature stays below 25°C.**

**Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days.**

Light, heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

### *Disposal*

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

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## Product description

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### *What it looks like*

Betahistine GH 16 mg are uncoated, round, biconvex, white to light creamy tablets, with a groove on one surface.

Betahistine GH 16 mg tablets are presented in PA/Al/PVC/Al blister packs containing 25 tablets.

### *Ingredients*

#### *Active ingredient*

Each tablet contains 16 mg betahistine dihydrochloride as the active ingredient.

#### *Other ingredients*

Betahistine GH tablets contain the following inactive (excipient) ingredients:

- colloidal anhydrous silica;
- microcrystalline cellulose;
- mannitol;
- citric acid;
- purified talc.

Betahistine GH tablets do not contain any lactose or gluten.

### *Australian Registration Numbers*

Betahistine GH 16 mg tablets: AUST R 212076.

### *Sponsor*

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