

BETASERT

Betahistine dihydrochloride

Consumer Medicine Information

What is in this leaflet

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

BETASERT is used to treat Meniere's Syndrome, 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.

BETASERT 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 BETASERT 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.

BETASERT is not addictive.

Before you take BETASERT

When you must not take it

Do not use BETASERT if you have an allergy to:

- Any medicine containing 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 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 BETASERT may pass into breast milk and therefore there is a possibility your baby may be affected.

Do not give BETASERT 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 use 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 BETASERT may interfere with each other.

These include:

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

These medicines may affect the way BETASERT works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any other medicines and what to be careful of which medicines to avoid while taking BETASERT.

If you have not told your doctor about any of these things, tell them before you take any BETASERT.

Taking BETASERT

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.

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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 BETASERT 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 BETASERT during or immediately after a meal.

If you take BETASERT 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, BETASERT 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 BETASERT 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 casualty at your nearest hospital if you think that you or anyone else may have taken too much BETASERT even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include nausea.

While you are taking BETASERT

Things you must do

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

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 BETASERT to anyone else, even if they have the same condition as you.

Do not use BETASERT tablets to treat any other complaints unless your doctor tells you to.

Do not stop taking BETASERT, or change the dosage, without 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.

Side effects

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

BETASERT helps most people, 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 treatment if you get some of the side effects.

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

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

Tell your doctor 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.

Stomach upsets can be overcome by taking BETASERT during meals.

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

- Skin reactions
- Difficulty breathing

These are 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.

After using BETASERT

Storage

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

If you take BETASERT 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 metres 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.

Product description

What BETASERT looks like

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

BETASERT 16 mg tablets are presented in OPA/Al/PVC/Al blister packs containing 25 tablets.

Ingredients

Each tablet contains 16 mg betahistine dihydrochloride as the active ingredient plus the following inactive (excipient) ingredients:

- Colloidal anhydrous silica
- Microcrystalline cellulose
- Mannitol
- Citric acid monohydrate
- Purified talc

BETASERT tablets do not contain any lactose or gluten.

Distributor

Arrotex Pharmaceuticals
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Australian registration number:
AUST R 212080

This leaflet was prepared in March 2023