

PART III: CONSUMER INFORMATION**Pr BETAHISTINE****Betahistine Dihydrochloride Tablets, House Standard**

Read this carefully before you start taking BETAHISTINE and each time you get a refill. This leaflet is a summary and will not tell you everything about BETAHISTINE. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about BETAHISTINE.

ABOUT THIS MEDICATION**What the medication is used for:**

BETAHISTINE is used for reducing the episodes of recurrent vertigo (dizziness) associated with Ménière's disease.

What it does:

BETAHISTINE is a type of medicine called a histamine-analogue. It is thought to work by helping the blood flow in your inner ear, which lowers the build up of pressure. It is this build up of pressure in the ear which is thought to cause feelings of dizziness (vertigo), feelings of being sick (nausea and vomiting), ringing in the ears (tinnitus), and hearing loss or hearing difficulty suffered by people with Ménière's disease.

When it should not be used:

Do not use BETAHISTINE if:

- you are allergic (hypersensitive) to betahistine dihydrochloride or to any of the non-medicinal ingredients in the product.
- you have a peptic (stomach) ulcer or have a history of this condition.
- your doctor has told you that you have an adrenal gland tumour (called pheochromocytoma).

What the medicinal ingredient is:

Betahistine dihydrochloride

What the non-medicinal ingredients are:

Colloidal Anhydrous Silica, Crospovidone, Lactose Monohydrate, Microcrystalline Cellulose, Povidone and Stearic Acid

What dosage forms it comes in:

Tablets: 16 mg and 24 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use BETAHISTINE talk to your doctor, nurse or pharmacist if you:

- have or have had health problems in the past.
- you are taking medications, including ones you can take without a doctor's prescription e.g., natural or herbal remedies.
- suffer from bronchial asthma, since asthmatic patients should use BETAHISTINE with caution.

- have liver problems.
- are pregnant, plan to become pregnant, or are breastfeeding.
- are less than 18 years old.

Driving and using machines: BETAHISTINE is not likely to affect your ability to drive or use tools or machinery. However, remember that the disease for which you are being treated (recurrent vertigo associated with Ménière's disease) can make you feel dizzy or sick, and can affect your ability to drive and use machines. Do not drive or engage in hazardous activities if you are experiencing these symptoms.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with BETAHISTINE:

- antihistamines - these may lower the effect of BETAHISTINE. In addition, BETAHISTINE may lower the effect of antihistamines.
- monoamine-oxidase inhibitors (MAOIs) - used to treat depression or Parkinson's Disease. These may increase the amount of BETAHISTINE available in your bloodstream and your doctor may have to change your dose of BETAHISTINE.

PROPER USE OF THIS MEDICATION

It is very important to take BETAHISTINE exactly as your doctor has instructed. If you are not sure when or how many tablets to take each day, check with your doctor, nurse or pharmacist. It is recommended to take your dose at about the same time every day. BETAHISTINE is not recommended for use in children below 18 years of age.

BETAHISTINE can be taken with or without food. If BETAHISTINE causes upset stomach, take it with meals.

Usual adult dose:

The usual daily dose is 24 – 48 mg daily in divided doses.

BETAHISTINE 16 mg tablets - half to one tablet three times a day.

BETAHISTINE 24 mg tablets - one tablet twice a day.

Overdose:

If you think you have taken too much BETAHISTINE, contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget a dose, skip the missed dose. Take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, BETAHISTINE can cause side effects in some people. Most people have few or no side effects from BETAHISTINE. Side effects that do occur tend to be generally mild and do not last a long time.

Side effects include:

- skin rashes and itching
- stomach pain
- nausea, vomiting
- bloating, indigestion
- headache

After the release of BETAHISTINE on the market, there were few reports of patients experiencing drowsiness, heart palpitations or light-headedness, faintness or dizziness from a drop-in blood pressure during treatment with BETAHISTINE. It is unclear whether they resulted from the use of BETAHISTINE or other unrelated factors.

If any of these affect you severely, tell your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

| Symptom/effect | Talk with your healthcare professional | | Stop taking drug and get immediate medical help |
|------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------|-------------------------------------------------|
| | Only if severe | In all cases | |
| Rare Severe allergic reaction: rash, hives, itching, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing | | | ✓ |

This is not a complete list of side effects. For any unexpected effects while taking BETAHISTINE, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Store between 15°C and 25°C. Protect from light and moisture.

Keep out of reach and sight of children.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Sanis Health Inc. at 1-866-236-4076.

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