

Package leaflet: Information for the patient**Betahistine Dihydrochloride DAWA
24mg, 16mg & 8mg Tablets**

(betahistine dihydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Betahistine is and what it is used for
2. What you need to know before you take Betahistine
3. How to take Betahistine
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1. What Betahistine is and what it is used for

The full name of this medicine is Betahistine dihydrochloride DAWA 24mg, 16mg & 8mg Tablets but within this leaflet it will be referred to as Betahistine.

Betahistine tablets contain betahistine dihydrochloride. This medicine is called a histamine analogue.

Betahistine is used for: Ménière's disease – the signs of this include:

- dizziness (Vertigo)
- ringing in the ears (tinnitus)
- hearing loss or hearing difficulty

This medicine works by improving blood flow in the inner ear. This lowers the buildup of pressure.

2. What you need to know before you take Betahistine**Do not take Betahistine if:**

- you are allergic to betahistine or to any of the other ingredients of this medicine (listed in section 6).
- you have high blood pressure due to an adrenal tumour (phaeochromocytoma).

Warnings and precautions

Talk to your doctor or pharmacist before taking Betahistine

- if you have a stomach ulcer
- if you have asthma
- if you have nettle rash, skin rash or a cold in the nose caused by an allergy, since these complaints may be exacerbated.
- if you have low blood pressure
- you are breast-feeding

If you suffer from any of the above conditions, consult your doctor about whether you may take Betahistine tablets. These groups of patients should be monitored by a doctor during treatment.

Children

Betahistine is not recommended for those under 18 years old.

Other medicines and Betahistine

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Anti-histamines - This is because in theory betahistine may not work properly. Also, betahistine may lower the effect of anti-histamines.
- Monoamine-oxidase inhibitors (MAOIs) – used to treat depression or Parkinson's disease. These may increase the exposure of Betahistine.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Betahistine.

Taking Betahistine with food and drink

You can take Betahistine with or without food. However, Betahistine can cause mild stomach problems (listed in section 4). Taking betahistine with food can help reduce stomach problems.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Betahistine if you are pregnant unless your doctor has decided that it is absolutely necessary. Ask your doctor for advice. Do not breast-feed while using Betahistine unless instructed by your doctor. It is not known if Betahistine passes into breast milk.

Driving and using machines

Betahistine is not likely to affect your ability to drive or use tools or machinery.

However, remember that diseases for which you are being treated with Betahistine (vertigo, tinnitus and hearing loss associated with Meniere's syndrome) can make you feel dizzy or be sick, and can affect your ability to drive or use machines.

Betahistine contains mannitol

This product contains mannitol which may have a mild laxative effect.

3. How to take Betahistine

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Your doctor will adjust your dose, depending on your progress.
- Keep taking your medicine. The medicine can take a while to start to work

How to take Betahistine

- Swallow the tablets with water.
- Take the tablet with or after a meal. However, Betahistine can cause mild stomach problems (listed in Section 4). Taking Betahistine with food can help reduce stomach problems.

How much Betahistine to take

Always follow your doctor's instructions because your doctor might adjust your dose.

The recommended dose is:

Adults

- Betahistine is available in three strengths, an 8 mg tablet, a 16 mg tablet and 24 mg tablet
- The recommended dose is 24 mg to 48 mg per day.
- If a high daily maintenance dose is needed, the 24mg strength can be used 2 times a day (1 tablet in the morning and evening). Daily dose should not exceed 48 mg.

If you take more than one tablet each day, spread your tablets evenly over the day. For example, take one tablet in the morning, one at midday and one in the evening.

Try to take your tablet at the same time each day. This will make sure that there is a steady amount of the medicine in your body. Taking at the same time will also help you remember to take your tablets.

Betahistine is not recommended for those under 18 years old.

If you take more Betahistine than you should

If you or someone else takes too many Betahistine tablets (an overdose), you may feel sick (nauseous), sleepy or have stomach pain. Talk to a doctor or go to a hospital immediately. Take the Betahistine pack with you.

If you forget to take Betahistine

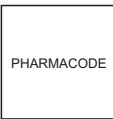
Wait until you have to take your next dose. Do not take a double dose to make up for a forgotten tablet.

How to stop taking Betahistine

Keep taking your tablets until your doctor tells you to stop.

Even when you start feeling better, your doctor may want you to carry on taking the tablets for some time to make sure that the medicine has worked completely.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.



Manufacturer
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This leaflet was revised in May 2022.

4. Possible side effects

Like all medicines, Betahistine can cause side effects (unwanted effects or reactions), but not everyone gets them. Very few adverse effects have been reported with betahistine.

The following serious side effects may occur during treatment with Betahistine:

Allergic reactions such as:

- swelling of your face, lips, tongue or neck.
- a red skin rash, inflamed itchy skin
- a drop in your blood pressure
- loss of consciousness
- difficulty breathing

If any of these side effects occur you should stop treatment immediately and contact your doctor.

Other side effects include:

Common (may affect up to 1 in 10 people):

- feeling sick (nausea)
- indigestion (dyspepsia)
- headache

Other side effects that have been reported with the use of Betahistine

Itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking Betahistine with food can help reduce any stomach problems.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Betahistine

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the carton and blister pack. The expiry date refers to the last day of that month.
- If your doctor stops your treatment, return any unused tablets to a pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Betahistine contains

Each tablet contains 8 mg, 16mg or 24 mg of Betahistine dihydrochloride.

The tablets also contain citric acid anhydrous, microcrystalline cellulose, mannitol (E421), silica colloidal anhydrous, purified talc.

What Betahistine looks like and contents of the pack

For Betahistine Dihydrochloride 24mg Tablets:

White colour, round (approx. 10.00mm) & biconvex uncoated tablet scored on one side with the embossing "II" on either sides of the score and plain on other side.

For Betahistine Dihydrochloride 16mg Tablets:

White colour, round (approx. 8.70mm) & biconvex uncoated tablet scored on one side with the embossing "I" on either sides of the score and plain on other side.

For Betahistine Dihydrochloride 8mg Tablets:

White colour, round (approx. 7.00mm) shaped FFBE tablets and plain on both sides.

Pack size:

Alu/PVC/ACLAR blister packs containing 84 or 120 tablets.
Alu/PVC/PVDC blister packs containing 84 or 120 tablets.

Marketing Authorisation Holder

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