

Package leaflet: Information for the user

Betahistine Dihydrochloride 24 mg orodispersible films

betahistine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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.

What is in this leaflet

1. What Betahistine Dihydrochloride is and what it is used for
2. What you need to know before you take Betahistine Dihydrochloride
3. How to take Betahistine Dihydrochloride
4. Possible side effects
5. How to store Betahistine Dihydrochloride
6. Contents of the pack and other information

1. What Betahistine Dihydrochloride is and what it is used for

Betahistine belongs to a group of medicines known as histamine analogues. It works by improving blood flow in the inner ear, which reduces the build up of pressure. It is this pressure in the inner ear which is thought to cause nausea, vertigo (dizziness), tinnitus (ringing in the ears) and hearing loss suffered by people with Meniere's disease. Betahistine Dihydrochloride is used in the treatment of these symptoms.

2. What you need to know before you take Betahistine Dihydrochloride

Do not take Betahistine Dihydrochloride

- if you are allergic to betahistine or any of the other ingredients of this medicine (listed in section 6).
- if you are taking an antihistamine to treat allergy. Betahistine may lower the effect of antihistamines
- if you have a tumour of adrenal gland called a phaeochromocytoma.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Betahistine Dihydrochloride.

Warnings and precautions

Talk to your doctor or pharmacist before taking Betahistine Dihydrochloride.

- if you suffer from bronchial asthma
- if you have a peptic ulcer (ulcer in stomach or upper part of the intestine, known as the duodenum), or have ever suffered from peptic ulcers in the past
- if you sometimes have allergic reactions such as hives (urticaria), skin rashes, or itchy or runny nose
- if you suffer from intense dizziness when you move your head in certain directions or dizziness in relation to various conditions related to the brain and spinal cord.

Other medicines and Betahistine Dihydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- salbutamol, to treat asthma
- medicine to treat or prevent malaria e.g pyrimethamine with dapson.
- an antihistamine (see section "Do not take")
- Monoamine-oxidase inhibitors (MAOIs) - used to treat depression or Parkinson's Disease. These may increase the exposure of Betahistine Dihydrochloride.

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

Betahistine Dihydrochloride with alcohol

You **should not** drink alcohol while being treated with this medicine, because there have been reported cases of interaction between this medicine with alcohol.

Pregnancy and breast-feeding

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.

Betahistine **should not** be taken during pregnancy or breast-feeding unless your doctor has decided that it is necessary.

Driving and using machines

Do not drive or operate machinery if you feel dizzy or drowsy, or you have eyesight problems while taking this medicine.

3. How to take Betahistine Dihydrochloride

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

The recommended dose is:

Adults (including the elderly):

Initial oral treatment is 8 mg to 16 mg three times daily, taken with food. Maintenance doses are generally in the range of 24 - 48 mg daily. Dosage can be adjusted to suit individual patient needs. The 24 mg strength is used twice per day (1 orodispersible film in the morning and 1 in the evening). This product is only for the patients who need a dose of 48 mg a day. In other cases, lower strengths can be used.

Use in children and adolescents

Betahistine should not be given to children and adolescents under 18 years because there is insufficient information on efficacy and safety.

How to take Betahistine

Swallow the orodispersible film with a glass of water. This medicine is best taken with food.

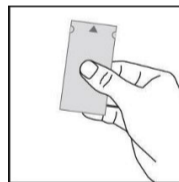
If you take more Betahistine than you should

Contact your doctor or nearest hospital emergency department immediately. Take the pack and any remaining orodispersible films with you. Symptoms of overdose include nausea, vomiting, indigestion, sleepiness, stomach pain, difficulty in controlling movements, seizures (fits), lung and heart problems at higher doses.

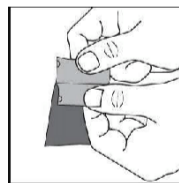
Instructions for use

Important: Do not handle the orodispersible film with wet hands!

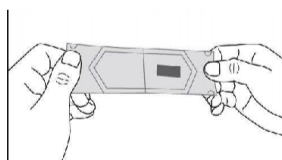
- a) Take the sachet, locate the arrow mark at one of the shorter sides and hold the sachet with this side facing up. The sachet is not sealed here.



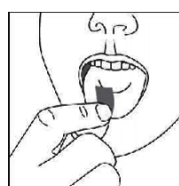
- b) Gently peel both parts of the sachet apart at the arrow mark. Now you can hold each between your thumb and your index finger using one hand for each part.



- c) Carefully tear both parts of the sachet into opposite directions until they are separated. The orodispersible film is now visible and placed on one of the separated sachet parts.



- d) Take the orodispersible film with dry fingers out of the sachet and put it in your mouth directly on your tongue. It will dissolve rapidly, so that it can be easily swallowed.



If you forget to take Betahistine Dihydrochloride

Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Betahistine Dihydrochloride

Speak to your doctor first before stopping this medicine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, stop taking Betahistine and tell your doctor immediately or go to your nearest hospital emergency department:

Not known (frequency cannot be estimated from the available data):

- allergic reactions including severe allergic reactions like anaphylaxis; symptoms may include hives (urticaria), rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue, sudden feeling of weakness (drop in blood pressure), unconsciousness

Other side effects include:

Very common (may affect more than 1 in 10 people):

- dry mouth
- diarrhoea

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

- nausea
- indigestion (dyspepsia)
- headache.

Rare (may affect up to 1 in 1,000 people):

- sleepiness
- a feeling of weakness

Very rare (may affect up to 1 in 10,000 people):

- a decrease in the number of some blood cells called platelets (these help in the clotting of blood).
- an increase in certain body enzymes (transaminases)

Not known (frequency cannot be estimated from the available data):

- mild gastric complaints such as vomiting, stomach pain and bloating. Taking betahistine with food can help reduce any stomach problems or speak to your doctor in case your dose needs adjusting.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: 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 Dihydrochloride

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Store in the original package in order to protect from light and moisture

Do not use this medicine after the expiry date which is stated on the pouch and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Betahistine Dihydrochloride contains**

- The active substance is betahistine dihydrochloride. Each orodispersible film contains 24 mg betahistine dihydrochloride.
- The other ingredients are Hypromellose, maltodextrin, povidone, masking flavor 501521 Firmenich (Flavour masking 501521 T), powderome lemon premium Firmenich, colloidal hydrated silica, sucralose, titanium Dioxide, glycerol and peppermint flavour 501500 TP0504 Firmenich (Mint flavour 501500 TP0504).

What Betahistine Dihydrochloride looks like and contents of the pack

Betahistine Dihydrochloride 24 mg orodispersible films are off-white to yellow colour square shape films. Each film is approximately 32 X 32 ±1 mm.

Each orodispersible film is packed in 4 ply laminate pack (i.e paper/PET/Alu/PE-sachet).

Betahistine Dihydrochloride 24 mg orodispersible films

84 orodispersible films

120 orodispersible films

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

DAWA Limited
5 Sandridge Close
Harrow, Middlesex
HA1 1XD
United Kingdom

Manufacturer

Wave Pharma Limited
4th Floor Cavendish House,
369 Burnt Oak Broadway,
Edgware, HA8 5AW Middlesex
United Kingdom.

This leaflet was last revised in 11/2025.

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Is this leaflet hard to see or
read?**

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the leaflet in a format suitable
for you.**

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