CP.BET.JNT.T.IS.V8P1

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

BETAHISTINE DIHYDROCHLORIDE 8mg AND 16mg TABLETS

Read all of this leaflet carefully before you start to take your medicine because it contains important information for you.
- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor, pharmacist or nurse.**
- **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, pharmacist or nurse. This includes any possible side effects not listed in the leaflet. See section 4.**

WHAT IS IN THIS LEAFLET

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

1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

The name of your medicine is Betahistine Dihydrochloride 8mg or 16mg Tablets. Betahistine Dihydrochloride is a type of medicine called a histamine analogue. It is used as a treatment for Ménière's syndrome, a condition caused by the pressure of excess fluid in the inner ear. Betahistine Dihydrochloride is thought to work by improving blood flow in the inner ear, which reduces the buildup of pressure. It is this pressure in the ear which is thought to cause the vertigo (dizziness), tinnitus (ringing in the ears) and hearing loss suffered by people with Ménière's disease

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE YOUR MEDICINE

Do not take your medicine if you:
- have ever had an allergic reaction to Betahistine Dihydrochloride or any of the other ingredients listed in Section 6, Contents of the pack and other information
- have phaeochromocytoma (a tumour associated with the adrenal gland which causes high blood pressure)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Betahistine Dihydrochloride if you:
- have or have ever had a stomach or intestinal ulcer
- have asthma
- have a condition called porphyria
- are pregnant or planning to become pregnant
- are breast-feeding

If any of the above applies to you, talk to your doctor before taking this medicine. Your doctor will tell you whether it is safe for you to start taking this medicine. Your doctor may also want to monitor your asthma while you take this medication.

Taking other medicines
Tell your doctor or pharmacist if you are taking, or have recently taken any other medicine, even those not prescribed by a doctor. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Antihistamines, which are used to relieve allergic conditions (e.g. terfenadine, diphenhydramine and chlorpheniramine).
  These may in theory lower the effect of this medicine. This medicine may also lower the effect of antihistamines.
- Monoamine-oxidase inhibitors (MAOIs) - used to treat depression or Parkinson's disease. These may inhibit metabolism of Betahistine Dihydrochloride.

Taking this medicine with food and drink
You can drink alcohol while taking this medicine.
You can take this medicine with or without food.

Pregnancy and breast-feeding
Do not take Betahistine Dihydrochloride 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 Dihydrochloride unless instructed by your doctor. It is not known if Betahistine Dihydrochloride passes into breast milk.

Driving and using machinery
It is unlikely that these tablets will affect your ability to drive or operate machinery. However, remember the diseases for which you are being treated with Betahistine Dihydrochloride (vertigo, tinnitus and hearing loss associated with Ménière's syndrome) can make you feel dizzy or be sick and can affect your ability to drive or use machines.

Important information about one of the ingredients in your medicine
These tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE YOUR MEDICINE

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 tablets should be swallowed whole with a sufficient quantity of liquid (e.g. one glass of water).
Take the tablet with or after a meal.

Adults
The recommended dose is 16mg three times daily (48mg), preferably taken with meals.

This medicine may take some time to have its full effect, so do not worry if you do not feel better right away. Your doctor may adjust the dose depending on your response. Do not adjust the dose unless told to do so by your doctor.

Use in Children and adolescents
This medicine should not be given to children under the age of 18 years.

How to stop taking your medicine
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 take more of your medicine than you should
If you take more tablets than you should, tell your doctor immediately or go to the nearest hospital. Take the medicine pack with you.

If you forget to take your medicine
Take your tablets as soon as you remember. If it is almost time for your next dose, wait until that is due and continue as normal. Do not take a double dose to make up for the forgotten dose. Do not take two doses within approximately two hours of each other.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
STOP taking Betahistine Dihydrochloride Tablets and see your doctor or nearest hospital casualty department IMMEDIATELY if you experience:
- an allergic reaction. Symptoms of an allergic reaction include; skin rashes, inflamed itchy skin, swelling of the lips, face, throat or tongue, difficulty breathing or swallowing.

Other common side effects (may affect up to 1 in 10) are:
- feeling sick (nausea)
- headaches
- indigestion (dyspepsia)

Other side effects (frequency not known-cannot be estimated from the available data)
- mild gastric complaints such as being sick (vomiting)
- abdominal pain and bloating
- stomach upsets
- itching and skin rashes
- swelling of the skin (angioneurotic oedema)
- hives

Taking this medicine with food can help reduce any stomach problems.
If any side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 by searching 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 YOUR MEDICINE

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
Do not store above 25°C. Store the tablets in the original package.
This medicine should preferably be locked in a cupboard or medicine cabinet.
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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What this medicine contains
- The active substance is Betahistine Dihydrochloride.
- The other ingredients are: povidone K90, microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, crospovidone and stearic acid.

What this medicine looks like and contents of the pack
Betahistine Dihydrochloride 8mg Tablets: White, circular, flat tablets marked with B8 on one side. Each tablet contains 8mg Betahistine Dihydrochloride.

Betahistine Dihydrochloride 16mg Tablets: White, circular, flat tablets marked with B16 on one side and a breakline on the other side. Each tablet contains 16mg Betahistine Dihydrochloride.

Pack sizes: 60, 84, 90, 100 and 120 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Kent Pharmaceuticals Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturers responsible for batch release
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

PL 08215/0201 and PL 08215/0202

This leaflet was last revised in July 2025.

CP.BET.JNT.T.IS.V8P1