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Betahistine Dihydrochloride

8mg & 16mg Tablets

Leaflet Size : 160 x 265 mm
MPLLBETXXXXTBCOMFPLXXX026V03

160 mm

265 mm

PHARMA CODE

XXXX

Pharmacode Reading Direction

PACKAGE LEAFLET: INFORMATION FOR THE USER
Betahistine Dihydrochloride 8mg & 16mg Tablets
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 Tablets is and what it is used for
2. What you need to know before you take Betahistine dihydrochloride Tablets
3. How to take Betahistine dihydrochloride Tablets
4. Possible side effects
5. How to store Betahistine dihydrochloride Tablets
6. Contents of the pack and other information

1. What Betahistine dihydrochloride Tablets is and what it is used for

These tablets contain Betahistine dihydrchloride.
They are used to treat vertigo, tinnitus (ringing in the ears) and hearing loss associated with Meniere's disease.
They work by reducing the pressure in your inner ear.

2. What you need to know before you take Betahistine dihydrochloride Tablets

Do not take Betahistine dihydrochloride tablets:
- if you are allergic (hypersensitive) to Betahistine dihydrochloride or any of the other ingredients of Betahistine dihydrochloride Tablets (listed in section 6). The symptoms of an allergic reaction include itching, nettle rash, wheezing or swelling of the hands, throat, mouth or eyelids.
- if you have phaeochromocytoma (high blood pressure due to adrenal tumour).

If you think any of the above points apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

Warnings and Precautions
Talk to your doctor or pharmacist before taking Betahistine dihydrochloride Tablets
- if have a stomach ulcer
- if you suffer from asthma.
- if you suffer from conditions relating to lactose such as galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

Other medicines and Betahistine dihydrochloride tablets
Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Antihistamines, which are used to treat allergic conditions.
- Monoamine-oxidase inhibitors (MAOIs) – used to treat depression or Parkinson's disease. These may inhibit metabolism of Betahistine Dihydrochloride.

Pregnancy, breast-feeding and fertility
Ask your doctor for advice before taking Betahistine dihydrochloride tablet if you are pregnant or planning to become pregnant or you re breast feeding.

Driving and using machines
There is no indication that taking Betahistine dihydrochloride tablets affect the ability to drive and use machines. However, take care and, if affected, do not drive or operate machines.

Betahistine dihydrochloride tablets contains lactose
These tablets contain lactose which is a type sugar. Contact your doctor before taking these tablets if you are lactose intolerant.

3. How to take Betahistine dihydrochloride Tablets

Always take Betahistine dihydrochloride tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Swallow the tablets with water and always take with or after meal.

160 mm

PHARMA CODE

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Pharmacode Reading Direction

Usual dose for adults and the elderly:
The usual starting dose of Betahistine dihydrochloride 16 mg three times a day.
After you have been taking treatment for a while your doctor may change the dose to between 24 and 48 mg a day.

If you take more Betahistine dihydrochloride tablets than you should
An overdose of this medicine may be dangerous. If you accidently take too many tablets tell your doctor or go to the nearest hospital casualty department immediately. The symptoms of a Betahistine dihydrochloride tablets overdose are nausea, vomiting, digestion problems, coordination problems and – with higher doses – fits.

If you forget to take Betahistine dihydrochloride tablets
If you forget to take a dose at the right time take it as soon as you remember and if it is almost time for your next dose, wait until that is due then go on as before. Do not take a double dose to make up for the forgotten dose.

If you stop taking Betahistine dihydrochloride tablets
Do not stop taking your Betahistine dihydrochloride tablet without talking to your doctor.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, these tablets can cause side effects, although not everybody gets them.

The following serious side effects may occur during treatment with Betahistine:
Allergic reactions such as: Swelling of your face, lips, tongue or neck. This may cause difficulty in breathing.
A red skin rash, inflamed itchy skin.
If any of these side effects occur you should stop treatment immediately and contact your doctor.

Common side effects (may affect up to 1 in 10 people):
Nausea, indigestion and headache

Other side effects
Itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating.
Taking Betahistine dihydrochloride tablets with meal can help reduce any stomach problems.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or 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.

5. How to store Betahistine dihydrochloride Tablets

Do not store above 30° C. Do not put them into another container as they might get mixed up. Keep out of the sight and reach of children.
Do not use Betahistine dihydrochloride tablets after the expiry date which is stated on the carton.
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 dihydrochloride tablets contains
The active substance is betahistine dihydrochloride (8mg or 16mg). The other ingredients are lactose, maize starch, microcrystalline cellulose, citric acid, crospovidone, povidone and sodium stearyl fumarate.
Betahistine dihydrochloride tablets are gluten free.

What Betahistine dihydrochloride tablets look like and contents of the pack
Betahistine dihydrochloride tablets are round white tablets. The 8mg tablets have 'R3' stamped on one side with a scoreline on the other and the 16mg tablets have 'R4' stamped on one side with a scoreline on the other.

Betahistine dihydrochloride 8 mg and 16mg tablets are available in packs of 84, 100 and 120 Tablets.
Not all pack sizes may be marketed.

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If you would like this leaflet in a different format please contact the Marketing authorisation holder as listed above.

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