

PACKAGE LEAFLET: INFORMATION FOR THE USER

Histabentine 8 mg/16 mg 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 any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Histabentine is and what it is used for
2. Before you take Histabentine
3. How to take Histabentine
4. Possible side effects
5. How to store Histabentine
6. Further information

1. What Histabentine is and what it is used for

Histabentine contains betahistine. This medicine is called a histamine analogue. It is used to treat:

- dizziness (vertigo)
- ringing in the ears (tinnitus)
- hearing loss suffered by people with Ménière's disease

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

2. Before you take Histabentine

Do not take Histabentine if:

- You are allergic to any of the ingredients in the tablets (see section 6 for further details).
 - You have high blood pressure due to an adrenal tumour (phaeochromocytoma).
- If any of the above applies to you, do not take this medicine and talk to your doctor.

Take special care and tell your doctor if:

- you have a stomach ulcer
- you have asthma
- you are pregnant or planning to become pregnant
- you 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 Histabentine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have taken 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 - these may (in theory) lower the effect of Histabentine. Also, Histabentine 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 Histabentine.

Taking Histabentine with food and drink

You can take Histabentine with or without food.

Pregnancy and breast-feeding

Do not take Histabentine 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 Histabentine unless instructed by your doctor. It is not known if Histabentine passes into breast milk.

Driving and using machines

Histabentine 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 Histabentine (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.

3. How to take Histabentine

How to take Histabentine

- Swallow the tablets with water.
- Preferably take the tablet with a meal.

How much Histabentine to take

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

- Histabentine is available in two strengths, an 8 mg tablet and a 16 mg tablet.
- The usual starting dose is 16 mg three times a day (48 mg).
- Your doctor may lower your dose to 8 mg three times a day (24 mg).

Keep taking your tablets. The tablets can take a while to start to work.

Histabentine is not recommended for those under 18 years old.

How to stop taking Histabentine

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 Histabentine than you should

If you or someone else takes too much Histabentine (an overdose), talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Histabentine

If you miss a tablet, wait until the next dose is due. Do not try to make up for the dose you have missed.

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

4. Possible side effects

Like all medicines, Histabentine can cause side effects (unwanted effects or reactions), but not everyone gets them.

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

Allergic reactions such as:

- swelling of your face, lips, tongue or neck. This may cause difficulty 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 (at least 1 in 100 and less than 1 in 10 patients):

Nausea, indigestion, headaches.

Other side effects

Itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking Histabentine 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Histabentine

- Keep out of the reach and sight of children.
- This medicine should preferably be locked in a cupboard or medicine cabinet.
- Do not use the tablets after the expiry date which is printed on the carton and blister pack.
- Store below 30°C and keep them in the original package.
- 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. Further information

What Histabentine contains

The active drug substance is betahistine dihydrochloride. Each tablet contains 8 or 16 mg of betahistine dihydrochloride.

The other ingredients are: Lactose monohydrate, Cellulose microcrystalline (E-460i), Povidone K-90 (E-1201), Silica colloidal anhydrous, Crospovidone, Stearic acid and Talc.

What Histabentine looks like and contents of the pack

Histabentine 8 mg is presented as white, round-shaped tablets with 'B8' imprinted on one face of the tablet.

Histabentine 16 mg is presented as white, round-shaped tablets with a score line in one side. Tablets can be divided in two equal doses. Histabentine 16 mg tablets have 'B16' imprinted on one face of the tablet.

Histabentine 8 mg is supplied in packages containing 60 tablets, in 10 tablets blister packs.

Histabentine 16 mg is supplied in packages containing 30 tablets, in 10 tablets blister packs.

Marketing Authorisation Holder and Manufacturer:

Laboratorios Cinfa, S.A.
Olaz Chipi, 10. Polígono Industrial Areta
31620 Huarte-Pamplona (Navarra) SPAIN

This leaflet was revised in June 2016.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

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