

Package leaflet: Information for the user
By-Vertin 8mg tablets
By-Vertin 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 By-Vertin is and what it is used for
2. What you need to know before you take By-Vertin
3. How to take By-Vertin
4. Possible side effects
5. How to store By-Vertin
6. Contents of the pack and other information

1. What By-Vertin is and what it is used for

Betahistine is a medicine that is used to treat Ménière's syndrome, symptoms of which may include dizziness, ringing in the ears, loss of hearing and nausea.

2. What you need to know before you take By-Vertin

Do not take betahistine

- if you are allergic to betahistine or any of the other ingredients of this medicine (listed in section 6)
- if you have a phaeochromocytoma, a rare tumour of the adrenal gland
- if you are under the age of 18

Warnings and precautions

- Talk to your doctor or pharmacist before taking Betahistine
- if you suffer or if you have suffered from a stomach ulcer (peptic 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
- if you are pregnant or planning to become
- if you are breast-feeding

If you suffer from any of the above conditions, consult your doctor about whether you may take betahistine.

These groups of patients should be monitored by a doctor during treatment.

Other medicines and Betahistine

An interaction means that the medicines or substances can affect the way each other works or the side effects when both are being taken at the same time.

So far no interactions of betahistine with other medicines have been observed.

It is possible that betahistine may influence the effect of antihistamines. Antihistamines are medicines that are used in particular for the treatment of allergies such as hay fever and for car sickness. Consult your doctor or pharmacist if you are using antihistamines (medicines against allergies) at the same time.

Caution is advised in the case of the concomitant use of betahistine and MAO-inhibitors. MAO-inhibitors are medicines that are used in particular for the treatment of depression.

Inform your doctor or your pharmacist if you are using (or have recently used) other medicines.

Pregnancy and breast-feeding

It is not known whether it is safe to use Betahistine during pregnancy. Therefore this medicine should not be used during pregnancy unless clearly necessary.

It is not known whether betahistine is excreted in the mother's milk. Therefore you should discuss breast-feeding with your doctor who can help you decide what is best for you and your baby based on the benefits and risks associated with this medicine.

Ask your doctor or pharmacist for advice before taking this or any other medicine.

Driving and using machines

By-Vertin is not likely to affect your ability to drive or use machines.

However, remember that diseases for which you are being treated with Betahistine (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.

By-Vertin contains lactose monohydrate

If you have been told by your doctor that you have a intolerance to some sugars, contact your doctor before taking this medicinal product

3. HOW TO TAKE BY-VERTIN

Always take By-Vertin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults

The usual starting dose is one to two 8 mg tablets or a half to one 16 mg tablet three times a day. The maintenance dose is usually in the range 24-48 mg daily.

It may take a couple of weeks before you notice any improvement.

How to use

It is best to take the tablets along with your food.

If you take more By-Vertin than you should

If you have taken more than the prescribed dose, consult your doctor.

The symptoms of a betahistine overdose up to 640 mg may be mild to moderate, such as nausea, drowsiness, vomiting, digestion problems, abdominal pain and coordination problems. Higher doses of betahistine may cause more serious symptoms, such as convulsions, heart or lung problems and fits.

If you forget to take By-Vertin

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur most frequently (affecting up to 1 in 10 people):

Gastrointestinal tract

Nausea and dyspepsia

Nervous system

Headache

The frequency of the following side effects is unknown:

Skin

Hypersensitivity reactions (sometimes severe), oedema, skin rashes, itching

Gastrointestinal tract

Mild gastrointestinal complaints (such as vomiting, gastrointestinal pain, bloating, nausea, digestive problems) which normally can be dealt with by taking the dose during meals. Alternatively, in consultation with your doctor, the dose can be lowered.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie E-mail:

medsafety@hpra.ie

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

5. HOW TO STORE BY-VERTIN

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 blister and carton after "Do not use after" or "Exp.". The expiry date refers to the last day of that month.

Store By-Vertin 8 & 16mg tablets in the original package.

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. FURTHER INFORMATION

Contents of the pack and other information

What BY-VERTIN 8 & 16 contain

The active substance is betahistine dihydrochloride.

One tablet contains 8mg betahistine dihydrochloride.

One tablet contains 16mg betahistine dihydrochloride.

The other ingredients are povidone, microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, crospovidone and stearic acid.

What By-Vertin look like and the contents of the pack

By-Vertin 8: a cylindrical, biplane white tablet with bevel-edges on both sides, the inscription "B8" on one side and a plain reverse.

10 tablets in a blister strip, 5, 10 or 12 blister strips in a cardboard box or 14 tablets in a blister strip, 1 blister strip in a cardboard box.

By-Vertin 16: a cylindrical, biplane, white tablet with bevel-edges on both sides, the inscription "B16" on one side and a break groove on the other. The tablet can be divided into equal halves.

10 tablets in a blister strip, 2, 5 or 6 blister strips in a cardboard box or 14 tablets in a blister strip, 1, 3 or 6 blister strips in a cardboard box.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder

Fannin Limited, Fannin House, South County Business Park, Leopardstown, Dublin 18.

PA 1457/011/001: By-Vertin 8mg tablets

PA 1457/011/002: By-Vertin 16mg tablets

Manufacturer

Catalent Germany Schorndorf GmbH, Steinbeisstrasse 2, D-73614, Schorndorf, Germany.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Betahistine Sandoz 8 mg & 16 mg
Ireland:	By-Vertin 8 mg & 16 mg tablets
Italy:	Sincrover, compresse 8 mg & 16 mg
The Netherlands:	Betahistine.2HCl Disphar 8 & 16, tabletten 8 mg & 16 mg

This leaflet was last approved in {01/2017}.