

PACKAGE LEAFLET: Information for the patient

VERTIBET

Tablets – 8 mg, 16 mg

(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 gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1. WHAT VERTIBET IS AND WHAT IT IS USED FOR

Vertibet contains the active substance betahistine dihydrochloride which is a histamine analogue medicine that is used to treat symptoms of Ménière's syndrome such as:

- dizziness (vertigo);
- ringing in the ears (tinnitus);
- loss of hearing and nausea.

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

2. BEFORE YOU TAKE VERTIBET

Do not take Vertibet if:

- you are allergic to betahistine dihydrochloride or to any of the ingredients in the tablet (see section 6);
- you have high blood pressure due to an adrenal tumour (phaeochromocytoma).

Take special care with Vertibet

Ask your doctor before you take Vertibet if you:

- have a stomach ulcer;
- have asthma;
- are pregnant or planning to become pregnant;
- are breastfeeding.

Your doctor may want to monitor your asthma while you take Vertibet.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have taken any other medicines, including medicines obtained without a prescription, including herbal medicines.

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

- anti-histamines – these may lower the effect of Vertibet; also Vertibet, 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 Vertibet.

Taking Vertibet with food and drinks

You can take Vertibet with or without food.

Pregnancy and breast-feeding

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

Driving and using machines

Vertibet 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 Vertibet (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 some of the ingredients of Vertibet

Vertibet tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before you take this medicinal product.

3. HOW TO TAKE VERTIBET

Swallow the tablets with a glass of water. Take Vertibet exactly as your doctor has told you. Check with your doctor 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.

Dosage can be adjusted to suit individual patient needs. Sometimes improvement could be observed only after a couple of weeks of treatment.

Vertibet tablets are not recommended for use in children and adolescents below 18 years of age, as there are no data on efficacy and safety in these age group.

If you take more Vertibet than you should

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

If you forget to take Vertibet

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 stop taking Vertibet

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Vertibet can cause side effects, but not everyone gets them.

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

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 the treatment immediately and contact your doctor.

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

Not known side effects (frequency cannot be estimated from the available data): itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking Vertibet with food can help reduce any stomach problems.

5. HOW TO STORE VERTIBET

Keep out of the reach and sight of children!

Do not use Vertibet after the expiry date stated on the package.

Do not store above 25°C!

Keep in the original packaging to protect it from light and humidity!

6. FURTHER INFORMATION

What Vertibet 8 mg, 16 mg tablets contain

The active substance is betahistine dihydrochloride.

Each tablet contains 8 mg or 16 mg of betahistine dihydrochloride.

The excipients are: lactose monohydrate, maize starch, citric acid, crospovidone, povidone, microcrystalline cellulose, hydrogenated vegetable oil.

Content of the pack

Vertibet 8 mg: box with 30 tablets.

Vertibet 16 mg: box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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