

## Package leaflet: Information for the user

**Vertix, 8 mg, tablets**  
**Vertix, 16 mg, tablets**  
*Betahistini dihydrochloridum*

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

## **1. What Vertix is and what it is used for**

### **What Vertix is**

Vertix contains betahistine. Vertix is a type of medicine called a “histamine analogue”.

### **What Vertix is used for**

Vertix is a medicine that is used to treat Ménière’s syndrome, characterized by the following symptoms:

- dizziness (with nausea and vomiting)
- progressive loss of hearing
- ringing in the ears.

Symptomatic treatment of vestibular vertigo.

### **How Vertix works**

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

## **2. What you need to know before you take Vertix**

### **Do not use Vertix**

- if you are allergic to active substance or any of the other ingredients of this medicine (listed in section 6)
- if your doctor has told you that you have a tumour of the adrenal gland (phaeochromocytoma).
- if you are breast-feeding (also see the section on “Pregnancy, breastfeeding and fertility”)

If any of the above applies to you, do not take Vertix. You should check with your doctor or pharmacist if you are not sure before taking Vertix.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Vertix:

- if you suffer or if you have suffered from a stomach ulcer (peptic ulcer)
- if you have asthma

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before using Vertix.

Your doctor may want to monitor you carefully during treatment with Vertix.

### **Children**

Vertix is not recommended for use under the age of 18.

### **Other medicines and Vertix**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 Vertix with other medicines have been observed.

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

- Anti-histamines - they may (theoretically) affect the way Vertix works. Vertix may also decrease the action of anti-histamines.
- Monoamine-oxidase inhibitors (MAOIs) - used to treat depression or Parkinson's Disease. These may increase the exposure of Vertix.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Vertix.

### **Vertix with food and drink**

Vertix can be taken with or without food. However, Vertix can cause mild stomach problems (listed in Section 4). Taking Vertix with food can help reduce stomach problems.

### **Pregnancy, breast-feeding and fertility**

It is not known if Vertix affects an unborn baby.

- Stop taking Vertix and tell your doctor if you become pregnant or think you might be pregnant.
- Do not take Vertix if you are pregnant unless your doctor has decided that it is necessary.

It is not known if Vertix passes into breast milk.

- Do not breast-feed while taking Vertix unless instructed by your doctor.

### **Driving and using machines**

Vertix is not likely to affect your ability to drive or use tools or machinery.

However, remember that the diseases for which you are being treated with Vertix (Ménière's disease and dizziness) can make you feel dizzy or sick, and can affect your ability to drive and use machines.

### **Vertix contains 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 Vertix**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Your doctor will adjust your dose, depending on your progress.
- Keep taking your medicine. The medicine can take a while to start to work.

### **How to take**

- Swallow the tablets with water.
- Take the tablet with or after a meal. However, Vertix can cause mild stomach problems (listed in Section 4). Taking Vertix with food can help reduce stomach problems.

### **How much to take**

Vertix is available in two strengths: 8 mg, 16 mg. The usual dose is:

- Vertix 8 mg - one or two tablets three times a day.
- Vertix 16 mg – a half to one tablet two or three times a day.

If you take more than one tablet each day, spread your tablets evenly over the day. For example, take one tablet in the morning, one at midday and one in the evening. Try to take your tablet at the same time each day. This will make sure that there is a steady amount of the medicine in your body. Taking at the same time will also help you remember to take your tablets.

### **If you take more Vertix than you should**

If you have taken more Vertix than you should, nausea, drowsiness or abdominal pain may occur. If you are unsure, please contact your doctor.

### **If you forget to take Vertix**

- If you forget to take Vertix, take the next scheduled dose at the regular time.
- Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Vertix**

Don't stop taking Vertix without talking to your doctor, even if there is an improvement.

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. After taking this medicine, the following side effects may occur:

### **Allergic reactions**

If you have an allergic reaction, stop taking Vertix and see a doctor or go to a hospital straight away. The signs may include:

- a red or lumpy skin rash or inflamed itchy skin
- swelling of your face, lips, tongue or neck
- a drop in your blood pressure
- loss of consciousness
- difficulty breathing.

**Stop taking Vertix and see a doctor or go to a hospital straight away, if you notice any of the signs above.**

### **Other side effects include:**

**Common** (affects less than 1 in 10 people)

- feeling sick (nausea)
- indigestion (dyspepsia)
- headache.

### **Other side effects that have been reported with the use of Vertix**

- Mild stomach problems such as being sick (vomiting), stomach pain, stomach swelling (abdominal distension) and bloating. Taking Vertix with food can help reduce stomach problems.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i

Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warszawa, Poland, tel.: + 48 22 49 21 301, faks: + 48 22 49 21 309, e-mail: ndl@urpl.gov.pl.

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

## **5. How to store Vertex**

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 and on the blister after EXP. The expiry date refers to the last day of that month.

Store below 25°C in the original package.

Do not throw away 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. Contents of the pack and other information**

### **What Vertex contains**

The active substance is betahistine dihydrochloride.

One tablet of Vertex 8 mg contains 8mg betahistine dihydrochloride.

One tablet of Vertex 16 mg contains 16mg betahistine dihydrochloride.

The other ingredients are: povidone K90, microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, crospovidone (type A) and stearic acid.

### **What Vertex 8 mg and Vertex 16 mg looks like and contents of the pack**

**Vertex, 8 mg, tablets:** a round, white tablet with the inscription “B8” on one side. Available in packs containing 30, 50, 100, 120 tablets.

**Vertex, 16 mg, tablets:** a round, white tablet with the inscription “B16” on one side and a break groove on the other. Available in packs containing 20, 30, 42, 50, 60, 84 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Recordati Polska sp. z o.o.

ul. Królewska 16

00-103 Warszawa, Poland

#### **Manufacturer**

Catalent Germany Schorndorf GmbH

Steinbeisstrasse 2

D-73614 Schorndorf

Germany

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