

## **PACKAGE LEAFLET**

**Package leaflet: Information for the user**  
**Betaserc 24 mg orodispersible 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The full name of your medicine is Betaserc 24 mg orodispersible tablets. In this leaflet the shorter name Betaserc 24 mg ODT is used.

**What is in this leaflet**

1. What Betaserc 24 mg ODT is and what it is used for
2. What you need to know before you take Betaserc 24 mg ODT
3. How to take Betaserc 24 mg ODT
4. Possible side effects
5. How to store Betaserc 24 mg ODT
6. Contents of the pack and other information

**1. What Betaserc 24 mg ODT is and what it is used for**

**What Betaserc 24 mg ODT is**

Betaserc 24 mg ODT contains betahistine. Betaserc 24 mg ODT is a type of medicine called a “histamine-analogue”.

**What Betaserc 24 mg ODT is used for**

Ménière's disease - the signs of this include:

- feeling dizzy (vertigo) and feeling or being sick (nausea or vomiting)
- ringing in the ears (tinnitus)
- hearing loss or hearing difficulty.

Feeling dizzy - caused when the part of your inner ear which controls your balance is not working properly (called “vestibular vertigo”).

**How Betaserc 24 mg ODT works**

Betaserc 24 mg ODT works by improving the blood flow in your inner ear. The inner ear is one of the organs responsible for your sense of balance.

## 2. What you need to know before you take Betaserc 24 mg ODT

### Do not take Betaserc 24 mg ODT :

- If you are allergic to betahistine or to any of the other ingredients of this medicine (listed in section 6)
  - If your doctor has told you that you have an adrenal gland tumour (called “phaeochromocytoma”).
- Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Betaserc 24 mg ODT.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Betaserc 24 mg ODT:

- If you have ever had a stomach ulcer
- If you have asthma.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Betaserc 24 mg ODT. Your doctor may want to monitor you more closely while you take Betaserc 24 mg ODT.

### Children and adolescents

Do not give this medicine to children or adolescents below the age of 18 years.

### Other medicines and Betaserc 24 mg ODT

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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 Betaserc 24 mg ODT. Also, Betaserc 24 mg ODT 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 Betaserc 24 mg ODT.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Betaserc 24 mg ODT.

### Betaserc 24 mg ODT with food and drink

You can take Betaserc 24 mg ODT with or without food. However, Betaserc 24 mg ODT can cause mild stomach problems (listed in section 4). Taking Betaserc 24 mg ODT with food can help reduce stomach problems.

### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your pharmacist for advice before taking this medicine.

It is not known if Betaserc 24 mg ODT affects an unborn baby:

- Stop taking Betaserc 24 mg ODT and tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- Do not take Betaserc 24 mg ODT if you are pregnant unless your doctor has decided that it is necessary.

It is not known if Betaserc 24 mg ODT passes into human milk:

- Do not breast-feed if you are taking Betaserc 24 mg ODT unless your doctor tells you to.

### Driving and using machines

Betaserc 24 mg ODT is not likely to affect your ability to drive or use tools or machinery.

However, remember that the diseases you are taking this medicine for can make you feel dizzy or be sick, and can affect your ability to drive and use machines.

### **Betaserc 24 mg ODT contains**

- Aspartame (E951), a source of phenylalanine. This may be harmful for people with phenylketonuria.
- Sucrose. 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 Betaserc 24 mg ODT**

Always take this medicine exactly as your doctor has told you. You should 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**

- Place tablet on the tongue and allow to disintegrate before swallowing with or without water (according to your preference).
- You can take your tablet with or without food. However, Betaserc 24 mg ODT can cause mild stomach problems (listed in section 4). Taking Betaserc 24 mg ODT with food can help reduce stomach problems.

#### **How much to take**

The recommended dose is one tablet twice a day.

Spread your tablets evenly over the day. For example, take one tablet in the morning 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 Betaserc 24 mg ODT than you should**

If you take more Betaserc 24 mg ODT than you should, you may feel sick (nauseous), sleepy or have stomach pain. If you are worried, talk to your doctor.

#### **If you forget to take Betaserc 24 mg ODT**

- If you forget a dose, skip the missed dose. Take your next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Betaserc 24 mg ODT**

Do not stop taking Betaserc 24 mg ODT without talking to your doctor, even if you start to feel better. 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. The following side effects may happen with this medicine:

### Allergic reactions

If you have an allergic reaction, stop taking Betaserc 24 mg ODT 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 Betaserc 24 mg ODT and see a doctor or go to a hospital straight away, if you notice any of the signs above.**

### Other side effects include:

**Common** (may affect up to 1 in 10 people)

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

### Other side effects that have been reported with the use of Betaserc 24 mg ODT

- Mild stomach problems such as being sick (vomiting), stomach pain, stomach swelling (abdominal distension) and bloating. Taking Betaserc 24 mg ODT with food can help reduce 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. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Betaserc 24 mg ODT

- 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 blister pack. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions
- 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 to protect the environment.

## 6. Contents of the pack and other information

### What Betaserc 24 mg ODT contains

The active substance is betahistine dihydrochloride. Each tablet contains 24 milligrams (mg) of betahistine dihydrochloride. The other ingredients of Betaserc 24 mg ODT are microcrystalline cellulose, crospovidone (type A), citric acid anhydrous, colloidal anhydrous silica, talc, peppermint flavour, masking flavour (sucrose, E951 aspartame, E950 acesulfame potassium).

### What Betaserc 24 mg ODT looks like and contents of the pack

- Betaserc 24 mg orodispersible tablets are round, flat, white to yellowish, uncoated, with bevelled edges and without inscriptions. They have a diameter of about 9mm.

- Betaserc 24 mg ODT is available in packs of 20, 30, 50, 60 or 100 tablets. They are packed in blister strips of polyamide/aluminium/PVC and aluminium lidding foil.
- Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

[To be completed nationally]

<Name and address>

<Tel>

<Fax>

<E-mail>

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

< {Name of the Member State} > < {Name of the medicinal product} >

< {Name of the Member State} > < {Name of the medicinal product} >

**This leaflet was last revised in MM/YYYY**

[To be completed nationally]