

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Betaserc 16 mg tablets**  
**Betaserc 24 mg 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 Betaserc is and what it is used for
2. What you need to know before you use Betaserc
3. How to use Betaserc
4. Possible side effects
5. How to store Betaserc
6. Contents of the pack and other information

### **1. WHAT BETASERC IS AND WHAT IT IS USED FOR**

The group of medicines, to which Betaserc belongs, are medicines for the treatment of dizziness.

Betaserc is used in Ménière's disease. The symptoms of this are:

- feeling dizzy and feeling or being sick
- ringing in the ears
- hearing loss or hearing problems.

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

### **How Betaserc works**

The mechanism of action of Betaserc is only partially known. Research shows that Betaserc can prevent an attack of Meniere's disease or reduce the severity of attacks.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE BETASERC**

#### **Do not take Betaserc :**

- if you are allergic (hypersensitive) to betahistine (dichloride) or any of the ingredients of Betaserc (see section 6).
- if you have pheochromocytoma (a rare adrenal gland disorder).

Do not take this medicine if any of the above points apply to you. If you are not sure, ask your doctor or pharmacist for advice before taking Betaserc.

### **Warnings and precautions.**

Please note the following points before you start using Betaserc and tell your doctor.

- if you have symptoms that may indicate a stomach ulcer or if you had a stomach ulcer in the past
- if you have asthma.

If any of the above points apply to you (or if you are not sure), ask your doctor or pharmacist for advice before using Betaserc. Your doctor may wish monitor you closely if you use Betaserc.

### **Children**

The use of Betaserc is not recommended for people below 18 years of age.

### **Other medicines and Betaserc:**

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

Always tell your doctor or pharmacist if you are using any of the following medicines:

- Anti-histamines (medicines primarily used in the treatment of allergy such as hay fever and/or motion sickness). These can (in theory) reduce the effect of Betaserc. Betaserc may also reduce the effect of antihistamines.
- Monoamine-oxidase inhibitors (MAO Inhibitor) – medicines used to treat depression or to treat Parkinson's Disease. These can increase exposure to Betaserc.

If any of the above points apply to you or you are not sure, ask your doctor or pharmacist for advice before using Betaserc.

### **Betaserc with food and drink.**

You can take Betaserc with or without food. However, Betaserc may cause mild stomach complaints (see section 4). Taking it with food may help reduce stomach complaints.

### **Pregnancy and breast-feeding.**

It is not known whether Betaserc affects the unborn child.

- Stop using Betaserc and tell your doctor if you are pregnant or think you may be pregnant.
- Do not use Betaserc if you are pregnant, unless your doctor has told you it is needed.
- It is not known whether Betaserc passes into breast milk. Do not use Betaserc if you are breast-feeding unless your doctor has told you to.

### **Driving and using machinery:**

Betahistine is used in Meniere's disease. This condition may negatively affect your ability to drive and use machines. Betaserc is unlikely to affect your ability to drive and use machines.

## **3. HOW TO USE BETASERC**

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

- Your doctor may adjust the dosage, based on your results.
- Do not stop using Betaserc. It may take a while for the medicine to work.

### **How do I take Betaserc?**

- Take the tablet with water.
- You can take Betaserc with or without food. However, Betaserc may cause mild stomach-complaints (see section 4). Taking it with food may help reduce stomach complaints.

Dosing is individual. For adults 24-48 mg is administered daily in divided doses.

Betaserc is available in two strengths, 16mg tablets and 24mg tablets

- If you are taking Betaserc 16mg tablets the dose will be ½ - 1 tablet 3 times per day
- If you are taking Betaserc 24mg tablets the dose will be 1 tablet 2 times per day

Try to take your tablets at the same time each day. This will make sure that there is a steady amount of medicine in your body. It will also make it easier for you to remember to take your medicine.

**If you take more Betaserc than you should:**

If you take more Betaserc than you should, you may feel sick, or drowsy or get stomach ache. Contact your doctor if you are worried.

**If you forget to take Betaserc:**

If you miss a dose, do not take it at a later time. Take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose

**If you stop using Betaserc**

Do not stop using Betaserc without telling your doctor, even if you 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 medicines can cause side effects, although not everybody gets them. The following side effects may occur with the use of this medicine.

**Allergic reactions**

If you have an allergic reaction, stop taking Betaserc and go straight to your doctor or hospital. Symptoms of an allergy can be:

- A red and lumpy skin rash or burning itchy skin
- Swelling of your face, lips, tongue or neck
- Drop in your blood pressure.
- Loss of consciousness.
- Breathing difficulties.

**Stop using Betaserc and go straight to your doctor or hospital if you notice any of the above symptoms.**

**Other side effects include:**

**Common** (occurring in less than 1 in 10 patients but more than 1 in 100 people):

- Feeling sick (nausea)
- Heartburn
- Headache

**Other side effects reported with the use of Betaserc.**

- Mild stomach problems such as feeling sick (vomiting), stomach ache, swelling of the stomach and bloating.

Taking Betaserc 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 (see details below):

ADR Reporting

[www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

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

## 5. HOW TO STORE BETASERC

- Keep this medicine out of sight and reach of children
- This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.
- Do not use after the expiry date which is stated on the package after 'EXP'. The expiry date refers to the last day of that month.
- 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. CONTENTS OF THE PACK AND OTHER INFORMATION

### What Betaserc contains:

- **The active substance is** betahistine dihydrochloride. Each tablet contains 16 mg or 24 mg of betahistine dihydrochloride.
- **The other ingredients are** microcrystalline cellulose, mannitol E421, citric acid monohydrate, colloidal silica anhydrous, talc.

### What Betaserc looks like and contents of the pack

Betaserc 16 mg tablet:

A round, biconvex, scored, white to almost white tablet with beveled edges. The diameter is 8.5 mm, the tablet weight is about 250 mg. The inscription is 267 on either side of the score and on one tablet side

The tablet can be divided into equal halves.

Betaserc 24 mg tablet:

A round, biconvex, scored, white to almost white tablet with beveled edges and relevant inscriptions. The diameter is 10 mm, the tablet weight is about 375 mg. The inscription is 289 on either side of the score and one tablet side.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

16 mg tablets: 60 tablets in package.

24 mg tablets: 20 tablets in package.

Not all package sizes may be marketed.

### Marketing Authorisation Holder:

Viartis Healthcare Limited  
Damastown Industrial Park,  
Mulhuddart,  
Dublin 15, DUBLIN,  
Ireland

### Manufacturers:

Mylan Laboratories SAS

Route de Belleville  
Lieu-dit "Maillard"  
01400 Chatillon sur Chalaronne  
France

Betaserc is registered in Malta under MA1507/02801 (Betaserc 16mg) and MA1507/02802

If you have further questions about this medicine, please contact the local representative of the marketing authorisation holder.

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