

Package leaflet: Information for the user

Serc® 16 mg tablets

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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

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

1. What Serc is and what it is used for

Serc contains betahistine. Serc is a type of medicine called a "histamine analogue".

Serc is used for:

Ménière's disease – the signs of this include:

- feeling dizzy (vertigo)
- ringing in the ears (tinnitus)
- hearing loss or hearing difficulty

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

2. Before you take Serc

Do not take Serc if:

- you are allergic (hypersensitive) to betahistine or any of the other ingredients in the tablets (see section 6 for further details)
- you have high blood pressure due to an adrenal gland tumour (phaeochromocytoma)

If any of the above applies to you, do not take this medicine and talk to your doctor.

Take special care and tell your doctor if:

- you have ever had a stomach ulcer
- you have asthma
- you are pregnant or planning to become pregnant
- you are breast-feeding.

If any of the above applies to you, talk to your doctor or pharmacist before taking Serc. Your doctor may want to monitor you more closely while you take Serc. Your doctor will tell you whether it is safe for you to start taking this medicine.

Children

Serc is not recommended for those under 18 years old.

Taking other medicines

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

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

Anti-histamines - This is because in theory Serc may not work properly. Also, Serc 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 Serc.

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

Taking Serc with food and drink

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

Pregnancy and breast-feeding

It is not known if Serc affects an unborn baby:

Stop taking Serc and tell your doctor if you become pregnant or think you might be pregnant.

Do not take Serc if you are pregnant unless your doctor has decided that it is necessary.

It is not known if Serc passes into breast milk:

Do not breast-feed while using Serc unless instructed by your doctor. Ask your doctor for advice.

Driving and using machines

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

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

3. How to take Serc

Always take Serc 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 Serc

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

How much Serc to take

Always follow your doctor's instructions because your doctor might adjust your dose.

- Serc is available in two strengths – 8 mg tablets and 16 mg tablets.
- The usual dose is 24 mg to 48 mg per day:

8 mg tablets – one or two tablets three times a day.

16 mg tablets – half or one tablet 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. Serc is not recommended for use in children.

How to stop taking Serc

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 take more Serc than you should

If you or someone else takes too many Serc tablets (an overdose), you may feel sick (nauseous), sleepy or have stomach pain. Talk to a doctor or go to a hospital immediately. Take the Serc pack with you.

If you forget to take Serc

If you miss a dose, take it when you remember. If it's nearly time for your next dose, ignore the missed dose and carry on as normal. Do not try to make up for the dose you have missed. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Serc can cause side effects (unwanted effects or reactions), but not everyone gets them. Very few side effects have been reported with Serc.

Allergic reactions

If you have an allergic reaction, stop taking Serc 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 Serc 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 Serc

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

If any of the side effects become serious, or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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

5. How to store Serc

- 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 EXP or CAD. The expiry date refers to the last day of that month.
- This medicinal product does not require any special temperature storage conditions. Store 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

What Serc contains

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

What Serc looks like and contents of the pack

Serc 16 mg tablets are round, biconvex, scored and white with '267' imprinted on one face. The score line can be used to split the tablet in half.

Serc 16 mg tablets are available in packs of 90 tablets.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

The Manufacturer is:

Mylan Laboratories SAS, Route de Belleville Lieu dit Maillard, 01400 Châtillon-sur-Chalaronne, France.

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