

Serc® 8mg Tablets

Betahistine Dihydrochloride 8mg Tablets

(betahistine dihydrochloride)

Your medicine is known by one of the above names, but will be referred to as Serc throughout this:

Patient Information Leaflet

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.

In this leaflet:

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

1) What Serc is and what it is used for

Serc contains betahistine. This medicine is called a histamine analogue. It is used to treat:

- dizziness (vertigo)
- ringing in the ears (tinnitus)
- hearing loss suffered by people with Ménière's disease

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 to any of the ingredients in the tablets (see section 6 for further details).
- You have high blood pressure due to an adrenal 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 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 before taking this medicine.

Your doctor will tell you whether it is safe for you to start taking this medicine.

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

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. This includes herbal 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 Serc. 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.

Taking Serc with food and drink

You can take Serc with or without food.

Pregnancy and breast-feeding

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

Driving and using machines

Serc 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 Serc (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.

3) How to take Serc

How to take Serc

- Swallow the tablets with water.
- Preferably take the tablet with a meal.

How much Serc to take

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

- Serc is available in two strengths, an 8 mg tablet and a 16 mg tablet.
- The usual starting dose is 16 mg three times a day (48 mg).
- Your doctor may lower your dose to 8 mg three times a day (24 mg).

Keep taking your tablets. The tablets can take a while to start to work.

Serc is not recommended for those under 18 years old.

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 much Serc (an overdose), talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Serc

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 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.

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

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 treatment immediately and contact your doctor.

Common side effects (at least 1 in 100 and less than 1 in 10 patients): Nausea, indigestion, headaches.

Other side effects

Itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking Serc with food can help reduce any 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Serc

- **Keep all medicines out of the sight and reach of children.**
- Do not store above 25°C. Store in the original package. Protect from light.

- If your doctor stops your treatment, return any unused tablets to a pharmacist.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6) Further information

What Serc contains

Each tablet contains 8mg of betahistine dihydrochloride.

The tablets also contain the following: mannitol, microcrystalline cellulose, citric acid, anhydrous colloidal silica and talc.

What Serc looks like and contents of the pack

Serc 8mg Tablets are round, flat and white to almost white with '256' imprinted on the one face and 'Solvay logo' on the reverse.

Serc 8mg Tablets are available as blister packs of 60 tablets.

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POM

Who makes and repackages your medicine?

Your medicine is manufactured by Abbott Healthcare S.A.S., Route de Belleville, Lieu-dit "Maillard," 01400 Chatillon-sur-Chalaronne, France. Procured from within the EU by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS and repackaged by Primecrown Ltd, Northolt, UB5 5QS.

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