NEW ZEALAND CONSUMER MEDICINE INFORMATION

SERC®

betahistine dihydrochloride 16 mg tablet



What is in this leaflet

Please read this leaflet carefully before you start taking Serc.

This leaflet answers some common questions about Serc.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Serc against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What SERC is used for

Serc is used to treat a disorder of your inner ear. This disorder may include one or more of the following symptoms, in one or both ears:

- ringing in the ears (tinnitus)
- loss of clear hearing
- problems with balance (vertigo)

These symptoms may also be associated with nausea, vomiting and headache. Often these symptoms together are referred to as Meniere's Syndrome.

Serc contains the active ingredient betahistine dihydrochloride. It belongs to a group of medicines to help treat vertigo.

Serc works by improving the blood flow of the inner ear and restoring it to normal. It also acts on the nerve endings in the inner ear to normalise the way in which the nerves respond to outside influences.

Your doctor may have prescribed this medicine for another reason.

This medicine is not addictive.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take Serc

When you must not take it

Do not take Serc if you have an allergy to:

- any medicine containing betahistine dihydrochloride
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in Serc passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children

younger than 18 years have not been established.

Do not take this medicine if you a rare abnormality of the adrenal gland known as phaeochromocytoma.

Do not take this medicine if you have or have had a peptic ulcer.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- asthma
- you are currently using antihistamines
- a history of allergic skin conditions

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Serc.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a

prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Serc.

Some medicines may interfere with Serc These include:

- any anti-histamine medications, which are used to treat allergies and allergic reactions
- Monoamine-oxidase (MAO) inhibitors (a class of antidepressant medicines, such as selegiline).

These medicines may be affected by Serc or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Serc

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual adult starting dose is 8 mg to 16 mg taken three times a day. However your doctor may prescribe a different dose depending on the severity of your condition. The maximum recommended daily dose is 48 mg.

How to take it

Swallow the tablets with a full glass of water. Serc 16 mg tablets can be divided in half along the score line.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Serc can be taken with or without food. However if you get stomach upset from Serc, it is recommended to take tablets with meals

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you follow your doctor's instructions Serc should start working within a few days, although in some cases it may take a few weeks. The length of time that you should take Serc tablets varies from patient to patient. Some patients respond rapidly to treatment and others may take some time. Please be patient with your treatment and take your tablets regularly.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Serc

Things you must do

If you are about to be started on any new medicine, tell your

doctor and pharmacist that you are taking Serc.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor or pharmacist immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Serc to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Serc affects you.

This medicine may cause dizziness, and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or tiredness may be worse.

Serc is indicated to treat:

- ringing in the ears (tinnitus)
- loss of clear hearing

 problems with balance (vertigo)

These symptoms can also negatively impact your ability to drive, operate machinery or anything else that could be dangerous. Alcohol could also make these symptoms worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Serc. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include nausea, sleepiness, dry mouth, abdominal pain, and convulsions.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Serc.

It helps most people, but it may have unwanted side effects in a few people. All medicines have some unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- tiredness
- stomach upsets or pain
- indigestion or heart burn
- vomiting or nausea
- diarrhoea
- dizziness
- headache
- difficulty sleeping (insomnia)

The above list includes the more common side effects of your medicine.

Stomach upsets can be overcome by taking Serc during meals.

Tell your doctor as soon as possible if you notice any of the following:

- confusion
- hallucinations
- fainting
- blurred vision

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- skin reactions such as rash, itching, with or without blistering.
- difficulty breathing or shortness of breath.
- swelling of the eyes or lips, face, throat or any other body parts.
- convulsions
- irregular or fast heat-beat

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Serc

Storage

Keep your tablets in the pack until it is time to take them. If you the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Serc or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

SERC tablets 16 mg are white, round, scored, with "267" on either side of the score.

Serc 16 mg tablets are available in packs of 100 tablets.

Ingredients

Active ingredient:

Serc contains 16 mg of betahistine dihydrochloride as the active ingredient.

Inactive ingredients:

Serc also contains

- colloidal anhydrous silica
- microcrystalline cellulose
- mannitol
- citric acid monohydrate

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Serc is supplied in New Zealand by:

Viatris Ltd PO Box 11-183 Ellerslie AUCKLAND www.viatris.co.nz Telephone 0800 168 169

Date of Preparation

24 January 2022 (Based on datasheet dated 24 January 2022)

Trade name® is a Viatris company trade mark.