

PART III: CONSUMER INFORMATION

PrSERC® betahistine dihydrochloride tablets

Read this carefully before you start taking SERC® and each time you get a refill. This leaflet is a summary and will not tell you everything about SERC®. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about SERC®.

ABOUT THIS MEDICATION

What the medication is used for:

SERC® is used for reducing the episodes of recurrent vertigo (dizziness) associated with Ménière's disease.

What it does:

SERC® is a type of medicine called a histamine-analogue. It is thought to work by helping the blood flow in your inner ear, which lowers the build up of pressure. It is this build up of pressure in the ear which is thought to cause feelings of dizziness (vertigo), feelings of being sick (nausea and vomiting), ringing in the ears (tinnitus), and hearing loss or hearing difficulty suffered by people with Ménière's disease.

When it should not be used:

Do not take SERC® if:

- you are allergic (hypersensitive) to betahistine dihydrochloride or to any of the non-medicinal ingredients in the product.
- you have a peptic (stomach) ulcer or have a history of this condition.
- your doctor has told you that you have an adrenal gland tumour (called phaeochromocytoma).

What the medicinal ingredient is:

betahistine dihydrochloride

What the non-medicinal ingredients are:

citric acid, colloidal anhydrous silica, mannitol, microcrystalline cellulose, and talc.

What dosage forms it comes in:

Tablets: 16 mg, List No. 0W085, and 24 mg, List No. 0W086.

WARNINGS AND PRECAUTIONS

BEFORE you use SERC® talk to your doctor, nurse or pharmacist if you:

- have or have had health problems in the past.
- you are taking medications, including ones you can take without a doctor's prescription e.g. natural or herbal remedies.
- suffer from bronchial asthma, since asthmatic patients should use SERC® with caution.
- have liver problems.
- are pregnant, plan to become pregnant, or are breastfeeding.
- are less than 18 years old.

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 (recurrent vertigo associated with Ménière's disease) can make you feel dizzy or sick, and can affect your ability to drive and use machines. Do not drive or engage in hazardous activities if you are experiencing these symptoms.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with SERC®:

- antihistamines - these may lower the effect of SERC®. In addition, SERC® may lower the effect of antihistamines.
- monoamine-oxidase inhibitors (MAOIs) - used to treat depression or Parkinson's Disease. These may increase the amount of SERC® available in your bloodstream and your doctor may have to change your dose of SERC®.

PROPER USE OF THIS MEDICATION

It is very important to take SERC® exactly as your doctor has instructed. If you are not sure when or how many tablets to take each day, check with your doctor, nurse or pharmacist. It is recommended to take your dose at about the same time every day. SERC® is not recommended for use in children below 18 years of age.

SERC® can be taken with or without food. If SERC® causes upset stomach, take it with meals.

Usual adult dose:

The usual daily dose is 24 – 48 mg daily in divided doses.

SERC® 16 mg tablets - half to one tablet three times a day.

or

SERC® 24 mg tablets - one tablet twice a day.

Overdose:

If you think you have taken too much SERC[®] contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

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.

HOW TO STORE IT

Store at room temperature (15 to 30°C). Keep in a tightly closed container to protect from moisture.

Keep out of reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report on line at:**
www.healthcanada.gc.ca/medeffect
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789**
 - **Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at
<http://www.healthcanada.gc.ca/medeffect>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, SERC[®] can cause side effects in some people. Most people have few or no side effects from SERC[®]. Side effects that do occur tend to be generally mild and do not last a long time.

Side effects include:

- skin rashes and itching
- stomach pain
- nausea, vomiting
- bloating, indigestion
- headache

After the release of SERC[®] on the market, there were few reports of patients experiencing drowsiness, heart palpitations or light-headedness, faintness or dizziness from a drop in blood pressure during treatment with SERC[®]. It is unclear whether they resulted from the use of SERC[®] or other unrelated factors.

If any of these affect you severely, tell your doctor, nurse or pharmacist.

MORE INFORMATION

The most current version of this document plus the full Product Monograph, prepared for health professionals can be found at:

www.mylan.ca

or by contacting the sponsor, BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6 at: 1-844-596-9526

This leaflet was prepared by BGP Pharma ULC.

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SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical attention
		Only if severe	In all cases	
Rare	Severe allergic reaction: rash, hives, itching, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓

This is not a complete list of side effects. For any unexpected effects while taking SERC[®], contact your doctor, nurse or pharmacist.