Product Monograph

Including Patient Medication Information

[Pr]SERC®

betahistine dihydrochloride tablets

For Oral use

16 mg and 24 mg of betahistine dihydrochloride

Anti-vertigo Agent

BGP Pharma ULC

85 Advance Road

Etobicoke, Ontario

M8Z 2S6

Date of Authorization:

2026-03-25

Control Number: 299757

Recent Major Label Changes

None at time of the most recent authorization	

Certain sections (as indicated in section 2.1. of the PM Guidance) or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Table of Contents

Part 1: Healthcare Professional Information

1. Indications

SERC (betahistine dihydrochloride tablets) is indicated for:

- Reducing the episodes of recurrent vertigo associated with Ménière's disease.

1.1. Pediatrics

Pediatrics (< 18 years of age): SERC is not recommended for use in children below 18 years of age due to insufficient data on safety and efficacy (see 7 Warnings and Precautions, Special populations, Pediatrics).

1.2. Geriatrics

Geriatrics (> 65 years of age): Evidence from clinical studies and experience suggests that use in the geriatric population is associated with differences in safety or effectiveness (see 7 Warnings and Precautions, Special populations, Geriatrics).

2. Contraindications

SERC is contraindicated in:

- patients who are hypersensitive to betahistine or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 Dosage Forms, Strengths, Composition, and Packaging.
- patients with peptic ulcer and in patients with a history of this condition (see 7 Warnings and Precautions, Gastrointestinal).
- patients with pheochromocytoma.

4. Dosage and Administration

4.1. Dosing Considerations

- Mild gastric complaints (e.g. vomiting, gastrointestinal pain, abdominal distension and bloating), have been observed. These can normally be minimized or eliminated by taking the dose during meals or by lowering the dose.

4.2. Recommended Dose and Dosage Adjustment

- The usual daily dosage range is 24 to 48 mg administered orally in divided doses.
- Three Times Daily Dosing
  - 16 mg tablets: ½ to 1 tablet three times daily.
- Twice Daily Dosing
  - 24 mg tablets: 1 tablet twice daily.

- Hepatic Impairment: SERC is highly metabolized primarily by the liver. No pharmacokinetic data are

available in patients with hepatic impairment. Caution is advised with use of SERC in this population.

- Pediatrics (>18 years of age): Health Canada has not authorized an indication for pediatric use.

4.4. Administration

SERC can be taken with or without food.

4.5. Missed Dose

If a dose is missed, the missed dose should not be taken. The next dose should be taken at the usual time. A double dose should never be taken to make up for a forgotten dose.

5. Overdose

A few overdose cases (up to 640 mg), with mild to moderate symptoms of nausea, dry mouth, dyspepsia, abdominal pain and somnolence have been reported. Presumably, more serious complications (e.g. convulsion, pulmonary or cardiac complications) may occur in cases of intentional overdose of SERC (betahistine dihydrochloride) above 640 mg, especially in combination with other overdosed drugs. Standard overdose protocol / supportive measures should be followed.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
oral	tablet 16 mg, 24 mg	citric acid, colloidal anhydrous silica, L-cysteine hydrochloride, mannitol, microcrystalline cellulose, propyl gallate, and talc.

Description

SERC® 16 mg tablets are supplied as round, biconvex, scored, white to almost white tablets with bevelled edges and one side inscribed with 267 on either side of the score. The diameter of the tablet is 8.5 mm. The tablet can be divided into equal halves. The tablets are individually blister packaged and are provided in boxes of 100.

SERC® 24 mg tablets are supplied as round, biconvex, scored, white to almost white tablets with bevelled edges and one side inscribed with 289 on either side of the score. The diameter of the tablet is 10 mm. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses. The tablets are individually blister packaged and are provided in boxes of 100.

7. Warnings and Precautions

Driving and Operating Machinery

Although not studied in patients with Ménière's disease, in clinical studies using normal healthy volunteers without Ménière's disease, 72 mg of SERC taken three times daily for three days, had no or negligible effects on driving skills in a driving task. However, Ménière's disease itself can negatively affect the ability to drive and use machines.

Gastrointestinal

Several patients with a history of peptic ulcer have experienced an exacerbation of symptoms while using SERC. Although experiments in animals and in humans have shown that the gastrointestinal side effects associated with betahistine dihydrochloride are not related to gastric acid production, SERC is contraindicated in the presence of patients with peptic ulcer and in patients with a history of this condition.

Respiratory

Although clinical intolerance to SERC (betahistine dihydrochloride) tablets has been shown in a relatively few patients with bronchial asthma, caution should be exercised when giving the product to asthmatic patients.

7.1. Special Populations

7.1.1. Pregnancy

The safety of SERC in human pregnancy has not been established. Animal studies are insufficient with respect to effects on pregnancy, embryonal / foetal development, parturition and postnatal development. The potential risk for humans is unknown. Betahistine dihydrochloride should not be used during pregnancy unless the potential benefits to the mother outweigh the potential risk to the fetus.

7.1.2. Breastfeeding

It is unknown if betahistine dihydrochloride is excreted into human milk, however caution should be exercised as betahistine accumulates in the milk of lactating rat dams. The importance of the drug to the mother should be weighed against the benefits of nursing and the potential risks for the child.

7.1.3. Pediatrics

Pediatrics (< 18 years of age): The safety and efficacy of SERC in pediatric patients below 18 years of age have not been evaluated, therefore its use in this population is not recommended.

7.1.4. Geriatrics

Geriatrics (> 65 years of age): Limited data from clinical studies suggest that a dosage adjustment is unlikely to be required in this patient group. In general, however, the risk of adverse reactions to any drug may be greater in elderly patients as they are more likely to have decreased renal and/or hepatic function and are more likely to be taking concomitant medications. Therefore, as with all drugs, caution should be exercised in this patient population.

8. Adverse Reactions

8.1. Adverse Reaction Overview

The most common adverse reactions experienced with SERC (betahistine dihydrochloride) are nausea, dyspepsia and headache.

8.2. Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the frequencies of adverse reactions observed in the clinical trials may not reflect frequencies observed in clinical practice and should not be compared to frequencies reported in clinical trials of another drug.

Table 2 – Undesirable Effects Experienced in Betahistine Dihydrochloride–Treated Patients in Placebo-Controlled Clinical Trials*

System organ class/preferred term	Betahistine dihydrochloride tablets n = 770 (%)	Placebo n = 751 (%)
Gastrointestinal Disorders		
Dyspepsia	1.0	0.5
Nausea	1.8	0.5
Nervous System Disorders		
Headache	5.3	4.4

* Data represent adverse events reported from 23 placebo-controlled studies where the frequency of the adverse event was reported ≥ 1% in the Betahistine group and at a frequency at least ≥ 0.5% higher than placebo.

8.5. Post-Market Adverse Reactions

In addition to those events reported during clinical trials, the following undesirable effects have been reported spontaneously during post-marketing use and in scientific literature. A frequency cannot be estimated from the available data and is therefore classified as 'not known'.

Cardiac Disorders:	Ventricular extrasystoles*, hypotension*, including orthostatic and postural hypotension, tachycardia*
Gastrointestinal Disorders:	Mild gastric complaints (e.g. vomiting, gastrointestinal pain, abdominal distension and bloating)
Immune System Disorders:	Hypersensitivity reactions (e.g. anaphylaxis)
Nervous System Disorders:	Somnolence*, convulsions*, paraesthesia*, confusion and hallucinations*
Respiratory, Thoracic and Mediastinal Disorders:	Dyspnoea*
Skin and Subcutaneous Tissue Disorders:	Angioneurotic oedema, urticaria, skin rashes of various types, pruritus and Stevens Johnson syndrome*

* The causal relationship between SERC and the emergence of these events has not been established.

9. Drug Interactions

9.2. Drug Interactions Overview

No in vivo interaction studies have been performed. In vitro data revealed no inhibition of Cytochrome P450 enzymes.

9.3. Drug-Behaviour Interactions

The interaction of SERC with individual behavioural risks (e.g. cigarette smoking, cannabis use, and/or alcohol consumption) has not been studied.

9.4. Drug-Drug Interactions

The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Table 3 – Established or Potential Drug-Drug Interactions

Betahistine dihydrochloride	Source of evidence	Effect	Clinical comment
Antihistamines	T	Reduction of efficacy of either drug	Caution is recommended. As betahistine is an analogue of histamine, interaction of betahistine with antihistamines may in theory affect the efficacy of one of these drugs.
Drugs that inhibit monoamino-oxidase (MAO) including MAO subtype B (e.g. selegiline)	In vitro	Inhibition of betahistine dihydrochloride metabolism	Caution is recommended when using betahistine dihydrochloride and MAO inhibitors (including MAO-B selective) concomitantly.

Legend: T = Theoretical

9.5. Drug-Food Interactions

Following administration of betahistine dihydrochloride to healthy male subjects under fed conditions, the rate of absorption was slowed down and maximum concentrations (C_{max}) decreased, whereas the extent of absorption (AUC_{inf}) was not affected by food.

9.6. Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10. Clinical Pharmacology

10.1. Mechanism of Action

The mechanism of action of betahistine dihydrochloride is only partly understood. There are several plausible hypotheses that are supported by animal studies and human data:

Betahistine dihydrochloride affects the histaminergic system: Betahistine dihydrochloride acts both as a partial histamine H_1-receptor agonist and histamine H_3-receptor antagonist in neuronal tissue and has negligible H_2-receptor activity. Betahistine dihydrochloride increases histamine turnover and release by blocking presynaptic H_3-receptors and inducing H_3-receptor downregulation.

Betahistine dihydrochloride may increase blood flow to the cochlear region: Pharmacological testing in animals has shown that the blood circulation in the striae vascularis of the inner ear improves, probably by means of a relaxation of the precapillary sphincters of the microcirculation of the inner ear.

Betahistine dihydrochloride alters neuronal firing in the vestibular nuclei: Betahistine dihydrochloride was also found to have a dose dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei.

10.2. Pharmacodynamics

In ten healthy male volunteers, single oral doses of 8, 16, and 32 mg of betahistine dihydrochloride given in a placebo-controlled, double-blind crossover study produced dose-related effects on the vestibular system, as measured by electronystagmography (ENG). Maximal effects on the slow nystagmus phase were found 3 to 4 hours after drug intake. Nystagmus duration was reduced by a mean value of 35% (after 8 mg), 48% (16 mg), or 59% (32 mg); all reductions were statistically significant ($p<0.0005$).

Eleven patients with Ménière's disease were treated in a three month, open-label study of the pharmacological effects of betahistine dihydrochloride on hearing and ENG-recorded, rotation-induced nystagmus. The study participants took one, 8 mg tablet three times a day (total daily dose, 24 mg). The speed of the quick phase of eye shift pre-treatment versus that achieved at the end of the three-month treatment period was used as the parameter of effectiveness in this study. Hearing was evaluated pre- and post-treatment using three pure tone hearing levels (250, 500, 1000 Hz).

Hearing loss was less after treatment, but the difference did not achieve statistical significance. At some rates of acceleration and at all rates of deceleration, there was an increase in the mean eye shift per second; this increase reached statistical significance in six of the 12 tests.

Animal data

Studies of the effects on the cardiovascular system, the pulmonary system, the renal system, the gastrointestinal system, and the central nervous system all indicated that betahistine dihydrochloride produced effects similar to, but less potent than, those of histamine.

Following rapid intravenous (iv) administration of betahistine dihydrochloride, a brief fall in blood pressure was evoked in rats, guinea pigs, dogs, and cats. This hypotensive effect could be blocked by the administration of histamine H1-antagonists, but not by histamine H2-antagonists. When betahistine dihydrochloride was injected slowly into anaesthetized dogs, general blood pressure decreased while basilar blood flow increased by up to 200%. Pronounced increases in blood flow were

found in the coronary (225%), labyrinthine (161%), and communicating hepatic arteries (156%).

Intravenous doses of 0.2 to 0.4 mg/kg given to anaesthetized guinea pigs produced an increase in pulmonary resistance while large doses induced bronchoconstriction. Parenteral administration to guinea pigs at a dose of 0.2 mg/kg induced vasopermeability. Administration of an intraperitoneal dose of 40 mg/kg caused death by respiratory failure.

In the perfused baboon kidney, the addition of betahistine dihydrochloride to the perfusate produced increases in urine flow, osmotic clearance, urea and creatinine clearance.

Betahistine dihydrochloride doses of 80 to 1600 mcg/kg/min administered as a continuous infusion to dogs with Heidenhain pouches produced a slight increase in the rate of acid secretion corresponding to 8.8% to 17.6% of the maximum response to histamine. In dogs with gastric fistulae, an increase in acid secretion was obtained with a subcutaneous dose of 20 mg/kg betahistine dihydrochloride. This increase corresponded with that produced by 30 mcg /kg of histamine.

The effect of betahistine dihydrochloride on continuous avoidance behaviour in rats was compared with that of histamine. Betahistine dihydrochloride injected intraventricularly at a dose of 0.32 mg/animal and histamine at a dose of 0.08 mg/animal produced a significant increase in the avoidance rate; an increase was also observed after an intraperitoneal dose of 4.0 mg/kg betahistine dihydrochloride, but this did not achieve statistical significance. Betahistine dihydrochloride did not affect the righting reflex when given to newborn chicks at a dose of 100 mg/kg, while a dose of 50 mg/kg histamine produced sleep characterized by loss of the righting reflex.

10.3. Pharmacokinetics

The pharmacokinetic profile of betahistine dihydrochloride was studied in six healthy male volunteers. Tablets containing 8 mg of radio-labelled betahistine dihydrochloride were administered to the subjects following an overnight fast, 30 minutes before a standard breakfast. Urine was collected for at least 56 hours after dosing, and five blood samples were drawn from each volunteer at 1, 2, 3, 8, and 25 hours for the first two volunteers, and at 1, 2, 3, 5.5, and 8 hours for the next four subjects.

Total urinary excretion of the radio-label was 90.7%, and the urinary half life was 3.5 hours. More than 85% of the administered dose was excreted in the urine within 24 hours. Only one primary urinary metabolite was identified - 2-pyridylacetic acid. Maximum plasma levels of radioactivity were attained by the 1-hour sampling time; the plasma half life of the radio-label was 3.4 hours.

Absorption

Orally administered betahistine dihydrochloride is readily and almost completely absorbed from all parts of the gastro-intestinal tract. Under fed conditions C_{max} is lower compared to fasted conditions. However, total absorption of betahistine dihydrochloride is similar under both conditions, indicating that food intake only slows down the absorption of betahistine dihydrochloride.

Distribution

The percentage of betahistine dihydrochloride that is bound by blood plasma proteins is less than 5%.

Metabolism

After absorption, betahistine dihydrochloride is rapidly and almost completely metabolized into 2-pyridylacetic acid (2-PAA; which has no pharmacological activity). After oral administration of betahistine dihydrochloride the plasma (and urinary) levels of betahistine dihydrochloride are very low. Pharmacokinetic analyses are therefore based on 2-PAA measurements in plasma and urine. The

plasma concentration of 2-PAA reaches its maximum 1 hour after intake and declines with a half-life of about 3.5 hours.

Elimination

2-PAA is readily excreted in the urine. In the dose range between 8 and 48 mg, about 85% of the original dose is recovered in the urine. Renal or fecal excretion of betahistine dihydrochloride itself is of minor importance.

Recovery rates are constant over the oral dose range of 8 to 48 mg indicating that the pharmacokinetics of betahistine dihydrochloride are linear and suggesting that the involved metabolic pathway is not saturated.

Special populations and conditions

- **Pediatrics:** SERC (betahistine dihydrochloride) is not recommended for use in children below 18 years of age.
- **Geriatrics:** Limited data from clinical studies in this patient group is available, however, as with all drugs, caution should be exercised in this patient population.
- **Sex:** No sex related pharmacokinetic differences have been observed in adult patients studied.
- **Genetic polymorphism:** No data is available on genetic polymorphism.
- **Ethnic origin:** Pharmacokinetic differences due to ethnic origin have not been identified.
- **Hepatic Insufficiency:** No pharmacokinetic data are available in patients with hepatic impairment.
- **Renal Insufficiency:** No pharmacokinetic data are available in patients with renal impairment.

11. Storage, Stability, and Disposal

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.

Part 2: Scientific Information

13. Pharmaceutical Information

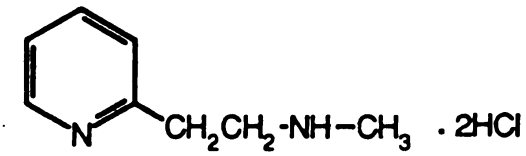
Drug Substance

Non-proprietary name of the drug substance(s): betahistine dihydrochloride

Chemical name: 2-[2-(methylamino)ethyl]pyridine dihydrochloride

Molecular formula and molecular mass: $C_8H_{12}N_2.2HCl$ 209.1

Structural formula:



Physicochemical properties: Betahistine dihydrochloride is a white to almost white crystalline product which is very hygroscopic. The product is very soluble in water, freely soluble in methanol and 96% methanol, and slightly soluble in isopropanol. The pKa values are 3.5 and 9.7. The substance melts at about 152°C.

16. Non-Clinical Toxicology

General toxicology

Acute Toxicity

The oral LD_{50} (Lethal Dose; LD_{50} is the amount of compound, given at a single dose, which causes the death of 50% [one half] of a group of test animals) for betahistine dihydrochloride is 3040 mg/kg in the albino rat. The intravenous LD_{50} is 5.1 mg/kg in the rabbit. Side effects in the nervous system were seen in dogs and baboons after intravenous doses at and above 120 mg/kg. Signs of toxicity included ataxia, salivation, inactivity, hyperpnoea, tremors, and cyanosis. Severe gastroenteritis was noted during pathology.

Long-Term Toxicity

Rat and Dog: In a six month study, dogs were given doses of up to 25 mg/kg/day. There were no significant abnormalities noted in any of the parameters assessed. In rats given doses of up to 500 mg/kg/day for 18 months, there were no significant abnormalities noted in any of the parameters assessed. Oral dosing up to and above 250 mg/kg, in dogs and in rats respectively, of betahistine dihydrochloride administered for 3 months did not result in adverse effects.

In investigational studies with betahistine dihydrochloride in rats over 6 months with doses starting at 13 mg/kg and above, hyperemia in some tissues was reported, namely liver, spleen and kidneys. Data presented in the literature are limited, therefore, the impact of this finding is not clear.

Dog and Baboon: Emesis was observed at 300 mg/kg and 120 mg/kg following oral and iv dosing respectively in dogs and sporadically in baboons.

Genotoxicity: In the studies conducted with betahistine dihydrochloride, no mutagenic effects have been observed.

Carcinogenicity: Special carcinogenicity studies were not performed with betahistine dihydrochloride. However, in two 18-month chronic toxicity studies in rats there was no indication of any tumors, neoplasms or hyperplasia in the histopathological examination. Therefore, betahistine dihydrochloride up to a dose of 500 mg/kg did not show any evidence for carcinogenicity in these limited 18-month studies.

Reproductive and developmental toxicology: Limited data are available for betahistine dihydrochloride on reproduction. In a one-generation study in rats, an oral dose of approximately 250 mg/kg/day betahistine dihydrochloride had no adverse effect on male and female fertility, implantation of foetuses, parturition and viability of pups during lactation. No abnormalities were noted in weaned rats. In pregnant rabbits treated orally with 10 or 100 mg/kg betahistine dihydrochloride from mating (gestation day 0) to gestation day 28, slight increases in fetal loss were observed in the two test groups and a slight increase in the incidence of reduced or unossified sternebrae and extra ribs were observed compared to untreated rabbits. Both effects were non-significant and within historical control data. No adverse effects were noted on implantations, vitality or weight of foetuses.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr SERC®

betahistine dihydrochloride tablets

This Patient Medication Information is written for the person who will be taking **SERC**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **SERC**, talk to a healthcare professional.

What SERC is used for:

SERC is used in adults to reduce the amount of episodes of vertigo (dizziness) associated with Ménière's disease.

How SERC works:

SERC belongs to a group of medicines called anti-vertigo agents. The symptoms of Ménière's disease, such as vertigo (dizziness), nausea, vomiting, tinnitus (ringing in the ears) and hearing loss or hearing difficulty, are thought to be caused by a build-up of fluid in the inner ear. SERC is thought to work by increasing blood flow to your inner ear and reducing the amount of fluid there. This helps to reduce the number of episodes of vertigo you have.

The ingredients in SERC are:

Medicinal ingredient: betahistine dihydrochloride

Non-medicinal ingredients: citric acid, colloidal anhydrous silica, L-cysteine hydrochloride,

mannitol, microcrystalline cellulose, propyl gallate, and talc.

SERC comes in the following dosage form:

Tablets: 16 mg and 24 mg.

Do not use SERC if:

- you are allergic to betahistine dihydrochloride or to any of the other ingredients in SERC.
- you have or have had stomach ulcers.
- you have a condition called pheochromocytoma (a tumour of the adrenal gland).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SERC. Talk about any health conditions or problems you may have, including if you:

- have asthma.
- have liver problems.
- are pregnant, think you might be pregnant or planning to become pregnant.

- are breast-feeding or planning to breast-feed.
- are 65 years of age or older.

Other warnings you should know about:

Driving and using machines: SERC is not likely to affect your ability to drive, use tools or machinery. However, Ménière's disease can make you feel dizzy or sick. This can affect your ability to drive and use machines. Do not drive or do special activities that require your attention if you experience these symptoms.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with SERC:

- medicines used to treat allergies.
- medicines known as monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease (e.g., phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegiline).

How to take SERC:

- Take SERC exactly as your healthcare professional has told you. If you are not sure, check with your healthcare professional.
- SERC can be taken with or without food. If SERC causes upset stomach, take it with meals.

Usual dose:

Usual daily dose: 24 mg to 48 mg in divided doses as per one of the dosing regimens below.

- If you are taking SERC 16 mg tablets: half to 1 tablet three times a day; or
- If you are taking SERC 24 mg tablets: 1 tablet twice a day.

Overdose:

If you think you, or a person you are caring for, have taken too much SERC, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or 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 missed dose.

Possible side effects from using SERC:

These are not all the possible side effects you may have when taking SERC. If you experience any side effects not listed here, tell your healthcare professional.

Side effects with SERC may include:

- skin rashes and itching
- gastrointestinal problems such as nausea or vomiting, stomach pain, bloating and indigestion
- headache
- drowsiness
- heart palpitations
- sudden drop in blood pressure (light-headedness, dizziness, faintness)
- confusion

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Rare			
Allergic reaction / Angioedema: difficulty swallowing or breathing, swelling of the face, lips, tongue, throat, hands, feet or genitals, wheezing, hives or skin rash, swelling of the digestive tract causing diarrhea, nausea or vomiting			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- 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.

If you want more information about SERC:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.viatris.ca; or by calling 1-844-596-9526.
- This information is current up to the time of the last authorization date shown below, but more current information may be available from the manufacturer.

This leaflet was prepared by BGP Pharma ULC.

Date of Authorization: 2026-03-25