PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

SERC® 24 tablets

Betahistine dihydrochloride

Contains sugar (75 mg mannitol per tablet).

Read all of this leaflet carefully before you start taking SERC 24 tablets

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse other health care provider.
- SERC 24 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SERC 24 is and what it is used for
2. What you need to know before you take SERC 24
3. How to take SERC 24
4. Possible side effects
5. How to store SERC 24
6. Contents of the pack and other information

1. What SERC 24 is and what it is used for

SERC 24 contains betahistine dihydrochloride which is an analogue of histamine.

SERC 24 is used to reduce the symptoms of vertigo associated with Ménière's syndrome. Vertigo is the sensation that you, or the environment around you, is moving or spinning.

SERC 24 works by improving the blood circulation in the inner ear.

2. What you need to know before you take SERC 24

Do not take SERC 24:

- If you are hypersensitive (allergic) to betahistine dihydrochloride or any of the other ingredients of SERC 24 (listed in section 6).
- If you have a stomach ulcer.
- If you have high blood pressure due to an adrenal tumour (phaeochromocytoma).

Warnings and precautions

Special care should be taken with SERC 24:

- If you have asthma. Your doctor may need to monitor your asthma while you take SERC 24.

Other medicines and SERC 24

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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

- Antihistamines – used to treat allergies.
- Monoamine-oxidase inhibitors (MAOIs) – used to treat depression or Parkinson's disease.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

It is not recommended that you take SERC 24 tablets if you are pregnant, as the safety of SERC 24 during pregnancy has not been determined.

It is not recommended that you take SERC 24 tablets while you are breast-feeding, as the safety of SERC 24 during breastfeeding has not been determined.

Driving and using machines

SERC 24 is not likely to affect your ability to drive or use machines. However, remember that the condition for which you are being treated with SERC 24 (vertigo associated with Ménière's syndrome) can make you feel dizzy or be sick, and can affect your ability to drive or use machines.

SERC 24 contains mannitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before giving SERC 24.

3. How to take SERC 24

Do not share medicines prescribed for you with any other person.
Always take SERC 24 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual daily dose is one 24 mg tablet twice a day. Your doctor may want to change this dosage according to your response.

If you take more SERC 24 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
An overdose of SERC 24 is likely to cause nausea, stomach pain, feeling tired, fits or heart problems.

4. Possible side effects

SERC 24 can have side effects.
Not all side effects reported for SERC 24 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SERC 24, please consult your health care provider for advice.

If any of the following happens, stop taking SERC 24 and tell your doctor immediately or go to the

casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SERC 24. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Severe allergic reactions.
- Nausea and dyspepsia.
- Headache.

Less frequent side effects:

- Rash, itching and hives.
- Swelling underneath the skin.

Side effects where the frequency is not known:

- Gastric complaints such as vomiting, stomach pain, bloating and swelling of the stomach. These can normally be dealt with by taking the dose during meals or by lowering the dose.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SERC 24.

5. How to store SERC 24

Store all medicines out of reach of children.

Store at or below 25 °C in the original container.

Store away from heat and direct light.

Do not store in the bathroom, near the kitchen sink, or in other damp places. Heat and moisture may cause the medicine to break down.

Do not use after the expiry date stated on the carton or blisters.

6. Contents of the pack and other information

What SERC 24 contains

Each tablet contains betahistine dihydrochloride 24 mg as the active ingredient.

The other ingredients are citric acid monohydrate, colloidal anhydrous silica, mannitol, microcrystalline cellulose and talc.

What SERC 24 looks like and contents of the pack

A round, biconvex, white to almost white tablet with bevelled edges, the standard inscription is 289 on either side of the score on one tablet-side.

SERC 24 is available in press through strips of PVC/PVDC/Aluminium containing 10 tablets.

Pack sizes: 20, 50 or 100 tablets per carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Abbott Laboratories S.A. (Pty) Ltd

Abbott Place, 219 Golf Club Terrace

Constantia Kloof, 1709

Johannesburg, South Africa

Tel: 011 858 2000

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