**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S3

**VERTIN® 24** Tablets

**Betahistine dihydrochloride**

Contains sugar (75 mg mannitol per tablet).

**Read all of this leaflet carefully before you start taking VERTIN® 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.
- VERTIN® 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 VERTIN® 24 is and what it is used for
2. What you need to know before you take VERTIN® 24
3. How to take VERTIN® 24
4. Possible side effects
5. How to store VERTIN® 24
6. Contents of the pack and other information

## 1. What VERTIN® 24 is and what it is used for

VERTIN® 24 is used to reduce the symptoms of vertigo associated with Ménière's syndrome.

Ménière's syndrome – the signs of this condition include:

- feeling dizzy (vertigo)
- ringing in the ears (tinnitus)
- hearing loss or hearing difficulty

It works by improving the blood circulation in the inner ear.

This lowers the build-up pressure.

## 2. What you need to know before you take VERTIN® 24

**Do not take VERTIN® 24:**

- if you are hypersensitive (allergic) to betahistine dihydrochloride or any of the other ingredients of VERTIN® 24 (listed in section 6).
- if you have a pheochromocytoma, a rare tumour of the adrenal gland.
- if you have an active stomach ulcer.

**Warnings and precautions**

Take special care with VERTIN® 24:

- if you have asthma. Your doctor may need to monitor your asthma while you take VERTIN® 24.

Do not take any antihistamine-containing medicines while you are taking VERTIN® 24 tablets (see **Other medicines and VERTIN® 24**).

**Other medicines and VERTIN® 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:

- Antihistamine containing medicines – used to treat allergies such as rash, colds and flu etc.
- Monoamine-oxidase inhibitors (MAOIs) – used to treat depression or Parkinson's disease.

**VERTIN® 24 with food and drink**

VERTIN® 24 can be taken with or without food. However, VERTIN® 24 can cause mild stomach problems. Taking VERTIN® 24 with food can help reduce stomach problems.

**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 VERTIN® 24.

Do not take VERTIN® 24 tablets if you are pregnant or breastfeeding as the safety of this medicine has not been determined.

**Driving and using machines**

VERTIN® 24 is not likely to affect your ability to drive or use tools or machines.

However, remember that the disease for which you are being treated with VERTIN® 24 can make you feel dizzy or sick, and can affect your ability to drive and use machines.

**VERTIN® 24 contains mannitol**

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

## 3. How to take VERTIN® 24

Do not share medicines prescribed for you with any other person.

Always take VERTIN® 24 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

***How to take VERTIN® 24:***

- Swallow the tablets with water.
- Take the tablet with or after a meal. However, VERTIN® 24 can cause mild stomach problems. Taking VERTIN® 24 with food can help reduce stomach problems.

The usual dose is one 24 mg tablet twice a day.

Your doctor may want to change this dosage according to your response.

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

Try to take your tablet at the same time each day. This will make sure that there is a steady amount of the medicine in your body. Taking at the same time will also help you remember to take your tablets.

**If you take more VERTIN® 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. Take VERTIN® 24 pack with you.

If you take too many VERTIN® 24 tablets (an overdose), you may feel sick (nauseous), sleepy or have stomach pain.

**If you forget to take VERTIN® 24**

Wait until you have to take your next dose. Do not take a double dose to make up for a forgotten tablet.

**If you stop taking VERTIN® 24**

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 VERTIN® 24 has worked completely.

If you have any further questions on the use of VERTIN® 24, ask your doctor or pharmacist.

## 4. Possible side effects

VERTIN® 24 can have side effects.

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

If any of the following happens, stop taking VERTIN® 24 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your face, lips, tongue or neck

- rash or itching
- a drop in your blood pressure
- loss of consciousness
- difficulty breathing

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

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- feeling sick (nausea)
- indigestion (dyspepsia)

*Less frequent side effects:*

- headache
- rash, itching, hives
- mild stomach problems such as being sick (vomiting), stomach pain, stomach swelling (abdominal distension) and bloating. Taking VERTIN® 24 with food can help reduce stomach problems.

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 VERTIN® 24.

## 5. How to store VERTIN® 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 remove the blisters from the carton until required.

Do not store in the bathroom, near the kitchen sink, or in other damp places.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What VERTIN® 24 contains

The active substance is betahistine dihydrochloride, 24 mg.

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

### What VERTIN® 24 looks like and contents of the pack

A round, biconvex, white to almost white tablet with bevelled edges, one side inscribed with 289.

VERTIN® 24 is available in press through strips of PVC/PVDC/Aluminium containing 20 tablets per carton.

### Holder of Certificate of Registration

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