PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

TREVIGO 24 mg TABLETS

Betahistine dihydrochloride

Read all of this leaflet carefully before you start taking TREVIGO 24 mg TABLETS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **TREVIGO 24 mg TABLETS** have 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.

1. WHAT TREVIGO 24 mg TABLETS CONTAIN

The active substance is betahistine dihydrochloride.

Each uncoated tablet contains betahistine dihydrochloride 24 mg.

The other ingredients of **TREVIGO 24 mg TABLETS** are cellulose microcrystalline, citric acid, crospovidone, mannitol, povidone, silica colloidal anhydrous, stearic acid and talc.

Contains mannitol 18,75 mg.

Sugar free.

2. WHAT TREVIGO 24 mg TABLETS ARE USED FOR

TREVIGO 24 mg TABLETS are used to treat vertigo (dizziness) associated with Ménière's syndrome. Vertigo is a condition that causes sufferers to have a sensation of rotation or movement of themselves or their surroundings. **TREVIGO 24 mg TABLETS** work by improving blood flow in the inner ear. This lowers the build-up of pressure.

3. BEFORE YOU TAKE TREVIGO 24 mg TABLETS

Do not take TREVIGO 24 mg TABLETS:

- If you are hypersensitive (allergic) to betahistine dihydrochloride, or any of the other ingredients of **TREVIGO 24 mg TABLETS**.
- If you have a stomach ulcer.
- If you suffer from pheochromocytoma (a tumour on the adrenal gland).

Take special care with TREVIGO 24 mg TABLETS:

- If you have asthma.
- If you have ever had a stomach ulcer.

Taking TREVIGO 24 mg TABLETS with food and drink:

- **TREVIGO 24 mg TABLETS** are preferably taken with meals.

Pregnancy and Breastfeeding:

- The safe use of **TREVIGO 24 mg TABLETS** during pregnancy and breastfeeding has not been determined.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **TREVIGO 24 mg TABLETS**.

Driving and using machinery

TREVIGO 24 mg TABLETS do not appear to make one sleepy or drowsy, so you can drive or operate machinery, if necessary. Please consult your doctor or pharmacist for advice.

Taking other medicines with TREVIGO 24 mg TABLETS:

- Do not take **TREVIGO 24 mg TABLETS** together with antihistamine medicines i.e., medicines used for the treatment of allergy.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary

or traditional medicines.)

4. HOW TO TAKE TREVIGO 24 mg TABLETS

Always take **TREVIGO 24 mg TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **TREVIGO 24 mg TABLETS** is too strong or too weak, talk to your doctor or pharmacist. Do not share medicines prescribed for you with any other person.

- **Adults (including the elderly):**
  - **TREVIGO 24 mg TABLETS** are preferably taken with meals.
  - Dosage is determined according to the individual patient's response. Depending on the severity of your complaints, your doctor will determine the necessary dose for the treatment of your disease.
  - The usual starting dose is 16 mg three times a day.
  - Thereafter, the usual recommended dose is 24 to 48 mg daily, taken in divided doses.
- **Children:**
  - **TREVIGO 24 mg TABLETS** should not be used in children.

If you take more TREVIGO 24 mg TABLETS than you should:

- The symptoms of overdose include nausea, vomiting and headache. Low blood pressure may occur.
- Treatment may include emptying the stomach.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of TREVIGO 24 mg TABLETS:

- Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

TREVIGO 24 mg TABLETS can have side effects.

Get emergency medical help immediately if you have any of these **signs of an allergic reaction:**

- Difficulty breathing; swelling of your face, lips, tongue, or throat.

- A red skin rash inflamed itchy skin; hives.

Other side effects include: Headache, mild gastric complaints such as vomiting, stomach pain and bloating.

Taking **TREVIGO 24 mg TABLETS** during meals or lowering the dose can help reduce any stomach problems.

Tell your doctor as soon as possible if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **TREVIGO 24 mg TABLETS**.

Not all side-effects reported for **TREVIGO 24 mg TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **TREVIGO 24 mg TABLETS**, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF TREVIGO 24 mg TABLETS

Store at or below 25 °C (room temperature).

Do not remove the blisters from the carton until required for use.

Keep the containers tightly closed.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF TREVIGO 24 mg TABLETS

TREVIGO 24 mg TABLETS:

Blister Pack:

Tablets are packed in blister packs (composed of OPA / aluminium foil / PVC film and printed aluminium foil).

Each blister contains 10 tablets.

The blisters will be further packed in pre-printed cartons with a package leaflet.

Pack size: 20's – Each carton contains 2 blisters of 10 tablets each.

HDPE Container Pack:

Tablets are packed in 40 ml white opaque round HDPE containers with white opaque polypropylene ribbed stock closures with a wad having an induction sealing liner, containing cotton coil.

The HDPE containers will be further packed in pre-printed cartons with a package leaflet.

Pack size: **20's -** One HDPE container contains 20 tablets.

Not all packs and pack sizes are necessarily marketed.

8. IDENTIFICATION OF TREVIGO 24 mg TABLETS

TREVIGO 24 mg TABLETS:

White to off–white round, uncoated tablets, debossed with 'X' and a break line on one side and '89' on the other side.

9. REGISTRATION NUMBER

TREVIGO 24 mg TABLETS: 45/5.6/0579

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

Date of Registration: 6 March 2014

Date of latest revision of the text as approved by Council: 6 March 2014

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