

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S3

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**TREVIGO 8 mg TABLETS**

**TREVIGO 16 mg TABLETS**

**TREVIGO 24 mg TABLETS**

Betahistine dihydrochloride

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

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

The active substance is betahistine dihydrochloride.

#### **TREVIGO 8 mg TABLETS:**

Each uncoated tablet contains betahistine dihydrochloride 8 mg.

#### **TREVIGO 16 mg TABLETS:**

Each uncoated tablet contains betahistine dihydrochloride 16 mg.

#### **TREVIGO 24 mg TABLETS:**

Each uncoated tablet contains betahistine dihydrochloride 24 mg.

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

### 2. WHAT TREVIGO TABLETS ARE USED FOR

**TREVIGO 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 TABLETS** work by improving blood flow in the inner ear. This lowers the build-up of pressure.

### 3. BEFORE YOU TAKE TREVIGO TABLETS

#### Do not take TREVIGO TABLETS:

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

#### Take special care with TREVIGO TABLETS:

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

#### Taking TREVIGO TABLETS with food and drink:

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

#### Pregnancy and Breastfeeding:

- The safe use of **TREVIGO 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 TABLETS**.

#### Driving and using machinery

**TREVIGO 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 TABLETS:

- Do not take **TREVIGO 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 TABLETS

Always take **TREVIGO 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 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 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 – 48 mg daily, taken in divided doses.

- **Children:**

- **TREVIGO TABLETS** should not be used in children.

**If you take more TREVIGO 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 TABLETS:**

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

#### 5. POSSIBLE SIDE EFFECTS

**TREVIGO 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, itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking **TREVIGO 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 TABLETS**.

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

## 6. STORING AND DISPOSING OF TREVIGO 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 TABLETS

### TREVIGO 8 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.

**Pack size:** 30's – Each carton contains 3 blisters of 10 tablets each.

#### **HDPE Container Pack:**

Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 30 tablets.

**Pack size: 30's** - One HDPE container contains 30 tablets.

#### **TREVIGO 16 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.

**Pack size: 30's** – Each carton contains 3 blisters of 10 tablets each.

##### **HDPE Container Pack:**

Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 30 tablets.

**Pack size: 30's** - One HDPE container contains 30 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.

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

##### **HDPE Container Pack:**

Tablets are packed in 40 ml HDPE containers with polypropylene closures with induction sealing wad, containing cotton coil. Each container contains 30 tablets.

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

### **8. IDENTIFICATION OF TREVIGO TABLETS**

#### **TREVIGO 8 mg TABLETS:**

White to off-white round, flat, uncoated tablets debossed with 'X' on one side and '87' on the other side.

#### **TREVIGO 16 mg TABLETS:**

White to off-white round, uncoated tablets, debossed with 'X' and a break line on one side and '88' on the other side.

#### **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/REFERENCE NUMBER**

**TREVIGO 8 mg TABLETS:** 45/5.6/0577

**TREVIGO 16 mg TABLETS:** 45/5.6/0578

**TREVIGO 24 mg TABLETS:** 45/5.6/0579

**10. NAME AND ADDRESS OF REGISTRATION HOLDER**

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**11. DATE OF PUBLICATION**

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