

PATIENT INFORMATION LEAFLET - INFORMATION FOR THE USER

Vertigon® 25mg Tablets

Promethazine teoclate

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Vertigon® Tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Vertigon® Tablets are and what they are used for

Vertigon® 25mg Tablets (hereinafter referred to as Vertigon® Tablets) are an anti-emetic (anti-sickness drug) for the relief of vertigo.

Vertigon® Tablets contain promethazine which belongs to a group of medicines called phenothiazines. It helps relieve the symptoms of dizziness and nausea.

2. Before you take Vertigon® Tablets

Do not give to a child under 2 years old.

Do not take Vertigon® Tablets if you have or have had:

- an allergic reaction to promethazine, any phenothiazine or any of the ingredients (see section 6 for more details)
- medicines for depression, known as Monoamine Oxidase Inhibitors (MAOIs) within the last 14 days
- CNS depression. People with CNS depression will seem sleepy or unconscious (including coma).

Take special care with Vertigon® Tablets and tell your doctor or pharmacist if you suffer with:

- glaucoma (increased pressure in the eye)
- epilepsy
- heart problems
- liver problems
- kidney or bladder problems
- a chest condition such as asthma or bronchitis
- severe headaches with blurred vision, severe stomach pains with vomiting, dizziness, difficulty with keeping

your balance, ringing in the ears or other ear problems as well as feeling sick

- a bad cough
- Reye's Syndrome or symptoms of Reye's Syndrome (including persistent vomiting, feeling tired or sleepiness).

Do not take Vertigon® Tablets for more than 7 days without contacting your doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You must tell your doctor or pharmacist if you are already taking any of the following medicines:

- anticholinergic agents
- medicines to help you sleep (hypnotics)
- medicines for depression, mental illness or anxiety (tricyclic antidepressants, sedatives)
- medicines for crampy stomach pains, Parkinson's disease or bladder problems.

If you are having skin tests for allergy, do not take this medicine as it interferes with the results. You should stop taking this medicine at least 72 hours before the skin tests.

Taking Vertigon® Tablets with food and drink

While taking Vertigon® Tablets, you should avoid drinking alcohol as the tablets will add to the effects of alcohol.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are breast-feeding your baby, you should not take Vertigon® Tablets, unless they have been recommended for you by a doctor. If you are breast-feeding your baby, Vertigon® Tablets may cause your baby to be irritable and excited. If you are having a pregnancy test, do not take this product as it interferes with the results.

Driving and operating machinery

These tablets may make you feel dizzy, sleepy, disorientated or confused or cause you to have a headache. You should not drive or operate machinery for the first few days, and until you are sure that you are not affected by these unwanted effects.

Important information about some of the ingredients in this product

These tablets contain sodium metabisulphite which may rarely cause hypersensitivity (allergic) reactions and bronchospasm (difficulty breathing). These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

(continued overleaf)

3. How to take Vertigon® Tablets

Your doctor may have prescribed this medicine. Always take Vertigon® Tablets as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For oral use. Adults

One tablet each night is usually enough, but two or three tablets may be required by some patients. These can be taken at intervals during the day, but it is often not necessary for more than 4 tablets to be needed in any 24 hour period.

Children over 10 years old

Give the lower adult dose (one tablet).

Children 5 - 10 years old

Give half the lower adult dose (half a tablet).

Do not take Vertigon® Tablets for more than seven days. Should symptoms persist for or do not improve after 7 days, talk to your doctor or pharmacist.

Vertigon® Tablets are not suitable for children under 2 years of age.

Avoid strong sunlight while taking this product as your skin may be more sensitive to the effect of the sun.

If you take more Vertigon® Tablets than you should:

Talk to your doctor or pharmacist immediately.

If you forget to take Vertigon® Tablets

If you forget to take a tablet, take one as soon as you remember. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines Vertigon® Tablets can cause side effects, although not everybody gets them.

If you experience any of the following side effects speak to your doctor **immediately**:

- severe rash, itching, swelling of the face, lips or mouth
- shortness of breath or difficulty breathing
- irregular heartbeats, low blood pressure (light-headed feeling when standing).

If you notice any of the following side effects speak to your doctor or pharmacist

- infections, fevers or sore throats which seem to go on a long time
- unexplained bruising or nose-bleeds
- if you develop a yellow colour of your skin, dark urine and yellowing of the whites of the eyes.

Other side effects may include:

- headache, dizziness, restlessness, confusion, you may feel tired or sleepy
- children may become over excited while taking this product
- occasionally some people, especially the elderly, may experience blurred vision, dry mouth or have difficulty passing water
- loss of appetite, upset stomach, nightmares
- cramp or muscles twitching or jerking, or the muscles become rigid

- unusual movements of the head and face muscles.

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

5. How to store Vertigon® Tablets

Keep this product out of the reach and sight of children.

Do not use after the expiry date printed on your pack.

Store in the original container.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Vertigon® Tablets contain

Each tablet contains the active ingredient promethazine teoclate 25mg.

Vertigon® Tablets also contain: lactose, sodium metabisulphite (E223), potato starch, dextrin, microcrystalline cellulose, stearic acid and magnesium stearate.

What Vertigon® Tablets look like and contents of the pack

Vertigon® Tablets are white to pale cream, plain, circular biconvex tablets marked 'PT' on one side with a score line on the reverse. They are available in cartons of 10 or 28 tablets and plastic containers of 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Manx Pharma Ltd., Taylor Group House, Wedgnoek Lane, Warwick, CV34 5YA, United Kingdom.

Manufacturer:

Manx Healthcare Ltd., Taylor Group House, Wedgnoek Lane, Warwick, CV34 5YA, United Kingdom.

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