

Verticlear Orodispersible Film 24mg

Betahistine Dihydrochloride 24mg

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What VETICLEAR is used for

VETICLEAR is used to treat Ménière's Syndrome that has the following symptoms

- Dizziness (vertigo) with nausea and vomiting
- Ringing in ears (tinnitus)
- Hearing loss

VETICLEAR is also used to treat vestibular vertigo

How VETICLEAR works

Betahistine belongs to a group of medicines known as histamine analogues. It works by improving blood flow in the inner ear, which reduces the build up of pressure. It is this pressure in the inner ear which is thought to cause nausea, vertigo (dizziness), tinnitus (ringing in the ears) and hearing loss suffered by people with Meniere's disease. VETICLEAR is used in the treatment of these symptoms.

Before you use VETICLEAR

- When you must not use it

Do not take VETICLEAR if

- if you are allergic to betahistine or any of the other ingredients of this medicine (listed in section 6).
- if you are taking an antihistamine to treat allergy. Betahistine may lower the effect of antihistamines
- if you have a tumour of adrenal gland called a pheochromocytoma.
- Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking VETICLEAR

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Betahistine should not be taken during pregnancy or breast-feeding unless your doctor has decided that it is necessary.

- Before you start to use it

Talk to your doctor or pharmacist regarding these before taking VETICLEAR

- if you suffer from bronchial asthma
- if you have a peptic ulcer (ulcer in stomach or upper part of the intestine, known as the duodenum), or have ever suffered from peptic ulcers in the past
- if you sometimes have allergic reactions such as hives (urticaria), skin rashes, or itchy or runny nose
- if you suffer from intense dizziness when you move your head in certain directions or dizziness in relation to various conditions related to the brain and spinal cord.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

- salbutamol, to treat asthma
- medicine to treat or prevent malaria e.g pyrimethamine with dapsone.
- an antihistamine (see section "Do not take")
- Monoamine-oxidase inhibitors (MAOIs) - used to treat depression or Parkinson's Disease. These may increase the exposure of VETICLEAR.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking VETICLEAR.

How to use VETICLEAR

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The dosage for adults is 48mg divided over the day.

24 mg Orodispersible film

1 Orodispersible film ; 2 times/day

The dosage should be individually adapted according to the response. Improvement can sometimes only be observed after a couple of weeks of treatment. The best results are sometimes obtained after a few months. There are indications that treatment from the onset of the disease prevents the progression of the disease and/or the loss of hearing in later phases of the disease. The 24 mg strength is used twice per day (1 Orodispersible film in the morning and 1 in the evening). This product is only for the patients who need a dose of 48 mg a day. In other cases, lower strengths can be used.

Use in children and adolescents

Betahistine should not be given to children and adolescents under 18 years because there is insufficient information on efficacy and safety.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue taking your medicine for as long as your doctor tells you.

Speak to your doctor first before stopping this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist

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- If you forget to use it

Take the next dose as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Contact your doctor or nearest hospital emergency department immediately. Take the pack and any remaining Orodispersible films with you. Symptoms of overdose include nausea, vomiting, indigestion, sleepiness, stomach pain, difficulty in controlling movements, seizures (fits), lung and heart problems at higher doses.

Instructions for use

Important: Do not handle the Orodispersible film with wet hands!

A. Peel to open the pouch



B. Take the strip out



C. Place the strip on the tongue



While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking VETICLEAR.

If you are going to have any surgery or procedure, including dental surgery, tell your surgeon, doctor or dentist that you are taking this medicine.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give VETICLEAR to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Do not drive or operate machinery if you feel dizzy or drowsy, or you have eyesight problems while taking this medicine. Vertigo, tinnitus and hearing loss associated with Ménière's syndrome negatively affect the ability to drive and use machines. In clinical studies specifically designed to investigate the ability to drive and use machines VETICLEAR had no or negligible effects.

However, rare reports of drowsiness associated with Betahistine have been made. Patients should be advised that if they are affected in this way they should avoid activities requiring concentration, such as driving or operating machinery.

VETICLEAR with alcohol

You should not drink alcohol while being treated with this medicine, because there have been reported cases

of interaction between this medicine with alcohol.

Side Effects

Like all medicines, VETICLEAR can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

The following side effects are very common if you take VETICLEAR :

Gastrointestinal disorders (dry mouth, diarrhoea)

The following side effects are common if you take VETICLEAR :

Nervous system disorders (headache)
Gastrointestinal disorders (nausea dyspepsia)

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of VETICLEAR

- Storage

Keep out of the sight and reach of children.

Store below 30°C. Protect from light and moisture

- Disposal

Do not use this medicine after the expiry date which is stated on the pouch and carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

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Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

VETICLEAR 24 mg is off-white to yellow color square shape films

- Ingredients

- Active ingredient

Each orodispersible film contains

Betahistine Dihydrochloride.

- Inactive ingredients

Hypromellose

Povidone

Masking flavor

Lemon flavor

Colloidal silica dioxide

Sucralose

Maltodextrin

Titanium Dioxide

Glycerol

Peppermint flavor and

Purified water

- MAL numbers:

Manufacturer

Shilpa Medicare Limited, Unit-VI
Avverhalli, Sompura Industrial Area,
Dabaspeta, Bengaluru, 562111, India.

Product Registration Holder

Duopharma Marketing Sdn. Bhd.
Lot No. 2,4,6,8 & 10, Jalan P/7,
Seksyen 13, Kawasan Perusahaan
Bandar Baru Bangi, 43650, Bandar
Baru Bangi, Selangor Darul Ehsan,
Malaysia.

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