

VOMITRON ORAL SOLUTION

VOMITRON SUPPOSITORIES

COMPOSITION

VOMITRON Oral Solution

Active ingredient: Each 5 mL of VOMITRON oral solution contains 5 mg of Ondansetron Hydrochloride equivalent to 4 mg of Ondansetron.

Excipients: Citric acid monohydrate, Sodium citrate dihydrate, Sodium benzoate, Sorbitol, Strawberry flavor, Purified water.

VOMITRON Suppositories

Each suppository contains:

Active ingredient: Ondansetron 16mg

Excipient: Hard fat.

PHARMACEUTICAL FORM

VOMITRON Oral solution

Oral solution, 30mL and 90mL bottle.

VOMITRON Suppositories

Box of 2 and 4 suppositories.

PHARMACOTHERAPEUTIC GROUP

Antiemetics and antinauseants, Serotonin [5-HT₃] antagonists.

INDICATIONS

VOMITRON is used for:

- The prevention of nausea and vomiting caused by chemotherapy or radiotherapy for cancer.
- The prevention and treatment of nausea and vomiting after surgery.

DOSAGE AND ADMINISTRATION

VOMITRON Oral Solution

Vomitron Oral Solution is not recommended in infants under 6 months of age.

- Prevention of moderate nausea and vomiting from chemotherapy

Adult: 10ml (8mg) administered 30 minutes

before the start of the chemotherapy, with a subsequent 8-mg dose (10ml) 8 hours after the first dose. Then administer 8mg (10ml) twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy.

Children (4 to 12 years): 5ml (4mg) administered 30 minutes before the start of chemotherapy, with a subsequent 4-mg dose (5ml) 4 and 8 hours after the first dose.

Then administer 4 mg (5ml) three times a day (every 8 hours) for 1 to 2 days after completion of chemotherapy.

- Prevention of more severe nausea and vomiting from chemotherapy

Adults: 30ml (24 mg) administered 30 minutes before the start of the chemotherapy

- Prevention of nausea and vomiting from radiotherapy

Adults: 10ml (8mg) administered 1 to 2 hours before radiotherapy with subsequent 8-mg doses (10ml) every 8 hours after the first dose. This can be given for up to 5 days

- Prevention of nausea and vomiting after surgery:

Adults: 20mL (16mg) administered 1 hour before anaesthesia.

VOMITRON Suppositories

Vomitron Suppositories are not recommended for children.

- Prevention of nausea and vomiting from chemotherapy

The recommended dose of VOMITRON Suppositories is one 16 mg suppository given 1 to 2 hours before treatment. On the following days, the usual dose is one suppository (16 mg) each day. This may be repeated for up to 5 days.

Patients with moderate or severe liver problems

The total daily dose should not be more than 10 ml (8mg).

If you forget to take **VOMITRON**, do not take a double dose to make up for a forgotten dose.

If you take more than you should, talk to your doctor or go to a hospital straight away.

CONTRAINDICATIONS

If you have a history of hypersensitivity to Ondansetron or to any of the excipients in this medicine.

If you are taking apomorphine (used to treat Parkinson's disease)

PREGNANCY AND BREAST FEEDING

VOMITRON is not recommended for use during pregnancy.

Breastfeeding is not recommended during treatment with VOMITRON, the ingredients can pass into breast milk.

WARNINGS AND PRECAUTIONS

Talk to your doctor or pharmacist before taking VOMITRON:

- If you are allergic to similar medicines such as dolasetron, granisetron and palonosetron;
- If you have a blockage in your gut or you suffer from severe constipation;
- If you had a history of heart problems;
- If you have an uneven heart beat (arrhythmias);
- If you have liver problems;
- If you have a problem with the levels of salts in your blood such as sodium, potassium, and magnesium.

INTERACTIONS

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Carbamazepine or phenytoin used to treat epilepsy.
- Rifampicin used to treat infections such as tuberculosis.
- Antibiotics such as erythromycin.
- Antifungals such as ketoconazole.
- Anti-arrhythmics such as amiodarone used to treat an uneven heartbeat.
- Beta-blocker medicines used to treat certain heart or eye problems, anxiety or prevent migraines.
- Tramadol a painkiller.

- Haloperidol or methadone medicines that affect the heart.
- Cancer drugs (especially anthracyclines and trastuzumab).
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram.
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine.

SIDE EFFECTS

Like all medicines, VOMITRON oral solution can cause side effects, although not everybody gets them.

If you have an allergic reaction, stop taking it and see a doctor straight away. The signs may include: sudden wheezing and chest pain or chest tightness, swelling of your eyelids, face, lips, mouth or tongue, skin rash - red spots or lumps under your skin (hives) anywhere on your body, collapse.

Other side effects include:

- **Very common (may affect more than 1 in 10 people):** Headache.

- **Common (may affect up to 1 in 10 people):** A feeling of warmth or flushing, constipation, changes to liver function test results (if you take VOMITRON with a medicine called cisplatin)

- **Uncommon (may affect up to 1 in 100 people):** Hiccups, low blood pressure (which can make you feel faint or dizzy), uneven heart beat, chest pain, seizures, unusual body movements or shaking.

- **Rare (may affect up to 1 in 1,000 people):** Feeling dizzy or light headed, blurred vision, disturbance in heart rhythm (sometimes causing a sudden loss of consciousness)

- **Very rare (may affect up to 1 in 10,000 people):** Poor vision or temporary loss of eyesight, which usually comes back within 20 minutes.

CONSERVATION

Vomitron Oral Solution

Store below 30°C.

Vomitron Suppositories

Store below 25°C.

Keep out of reach of Children