

Patient Information Leaflet for Human Medicines

SCHEDULING STATUS S4

VOMIDON TABLETS 10 mg

Domperidone

Contains sugar:

70,00 mg lactose monohydrate per tablet

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VOMIDON TABLETS has 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.

What is in this leaflet

1. What VOMIDON TABLETS is and what it is used for
2. What you need to know before you take VOMIDON TABLETS
3. How to take VOMIDON TABLETS
4. Possible side effects
5. How to store VOMIDON TABLETS
6. Contents of the pack and other information

1. What VOMIDON TABLETS is and what it is used for

VOMIDON TABLETS is used in adults and adolescents over 12 years of age and weighing over 35 kg for:

- Short term relief not exceeding 7 days for **stomach discomfort** due to food moving slowly through the stomach and intestines, where you may feel symptoms such as:
 - o fullness during or shortly after a meal
 - o a “heavy stomach”
 - o bloated feeling
 - o excessive belching
 - o passing wind (flatulence)
 - o nausea
 - o vomiting
 - o a burning feeling and/or pain in the stomach area
- Short term use not exceeding 7 days for **discomfort due to backflow of stomach acid**, where you may experience belching and/or heartburn
- Short term use not exceeding 7 days except when used for **nausea and vomiting** due to various causes including chemotherapy, radiotherapy or other medicines where use should not exceed 4 weeks.

2. What you need to know before you take VOMIDON TABLETS

VOMIDON TABLETS are unsuitable for use in children at or less than 12 years of age.

VOMIDON TABLETS are unsuitable for use in adolescents weighing less or 35 kg body weight.

Do not take VOMIDON TABLETS:

- if you are hypersensitive (allergic) to domperidone or any of the other ingredients in VOMIDON TABLETS (listed in section 6).
- if you suffer from a disease of the pituitary gland called prolactinoma.
- if you have severe stomach cramps or persistent black stools.

- if you have a liver disease.
- If you are taking certain medicines that slow down the breakdown (metabolism) of other medicines in the body and can affect your heart rhythm, such as:
 - itraconazole, ketoconazole, posaconazole or voriconazole, which are used to treat fungal infections
 - erythromycin, clarithromycin or telithromycin or quinolones which are antibiotics
 - amiodarone, a heart medicine
 - ritonavir or saquinavir which are medicines for HIV/AIDS
- if you have or had heart problems including heart failure, a previous heart attack, angina (chest pains), or heart rhythm disorders including a rapid or slow or irregular heart beat.

If you are not sure about any of these please consult your doctor.

Stop taking VOMIDON TABLETS and contact your doctor immediately if you experience an abnormal heart beat.

Warnings and precautions

Take special care with VOMIDON TABLETS:

- if you are elderly caution should be taken with VOMIDON TABLETS since you are at greater risk to serious cardiac effects with doses greater than 30 mg per day.
- if you are taking antacids or anti-secretory medicines simultaneously with VOMIDON TABLETS as this reduces the effects of VOMIDON TABLETS. Therefore VOMIDON TABLETS should be taken before meals and antacids or anti-secretory medicines taken after meals.

- if you have kidney impairment you may require a lower dose which will be calculated by the prescriber.

Stop taking VOMIDON TABLETS and contact your doctor immediately if you experience an abnormal heart beat.

Other medicines and VOMIDON TABLETS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not take VOMIDON TABLETS if you are taking certain medicines that slow down the breaking down (metabolism) of other medicines in the body and can also affect your heart rhythm; such as:

- fluconazole, itraconazole, ketoconazole, posaconazole or voriconazole, which are used to treat fungal infections
- erythromycin, azithromycin, clarithromycin or telithromycin or quinolone which are antibiotics
- amiodarone which is a heart medicine
- ritonavir or saquinavir which are medicines for HIV/AIDS.

If in doubt, ask your doctor or pharmacist for advice.

Tell your doctor or pharmacist if you are taking medicine to treat:

- fungal or bacterial infection
- heart problems
- malaria
- HIV/AIDS
- depression
- mental illness

- stomach problems
- cancer
- pain
- addictions

Your doctor will decide if these medicines can be taken together with VOMIDON TABLETS or if you will need to be monitored closely for heart problem side effects.

Tell your doctor if you are taking anticholinergics (medicines to treat allergy, asthma, incontinence, gastrointestinal cramps, muscular spasms, depression or sleep disorders, for example, dextromethorphan or diphenhydramine) as these may affect VOMIDON TABLETS.

Tell your doctor if you are taking medicine(s) for stomach acid. These medicines can be taken if you are also taking VOMIDON TABLETS but they should not be taken at the same time. You should take oral VOMIDON TABLETS before meals and the stomach acid medicine after meals.

Pregnancy, breast-feeding and fertility

The safety of use during pregnancy and lactation has not been established. VOMIDON TABLETS is excreted in human breast milk therefore breast feeding is not recommended for mothers who are taking VOMIDON TABLETS.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machines

Do not drive or operate machines if you feel tired, sleepy or dizzy after taking VOMIDON TABLETS.

VOMIDON TABLETS contains lactose monohydrate

VOMIDON TABLETS contains lactose and may not be suitable for people with:

- lactose intolerance (inability to digest lactose, which is a sugar found in milk and milk products);
- galactosemia or glucose-galactose malabsorption (inability to digest carbohydrates and sugars which are found in many foods including starches, milk and milk products)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take VOMIDON TABLETS

Do not share medicines prescribed for you with any other person.

Always take VOMIDON TABLETS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with VOMIDON TABLETS will last. Do not stop early because your symptoms may reappear. If you have the impression that the effect of VOMIDON TABLETS is too strong or too weak, tell your doctor or pharmacist.

It is recommended to take oral **VOMIDON TABLETS** 15 – 30 minutes before meals. If taken after meals, absorption of the medicine is somewhat delayed. Take VOMIDON TABLETS with some liquid.

You should always take the lowest amount of VOMIDON TABLETS that works for you and you should not take it for longer than seven days. Although the amount of VOMIDON TABLETS

you should usually take is described below, your doctor may adjust your dose to your personal needs.

When a doctor has prescribed VOMIDON TABLETS for you, the following information applies: If VOMIDON TABLETS are for nausea and vomiting, you should not usually need to take it for more than one week. Talk to your doctor if your nausea and vomiting lasts or more than one week.

If VOMIDON TABLETS are for stomach discomfort, stomach acid backflow or nausea and vomiting due to chemotherapy, radiotherapy or other medicines, do not take VOMIDON TABLETS for longer than 4 weeks without talking to your doctor.

Adults and adolescents \geq 35 kg:

Take 1 of the 10 mg tablets three times per day with water. **Do not take more than 3 tablets per day.** The maximum dose per day is 30 mg.

Formulation (domperidone per unit)	Dosage	Maximum dose per day
Uncoated tablet (10 mg/tablet)	1 tablet three to four times a day	30 mg (3 x 10 mg tablet)

Using VOMIDON TABLETS in infants and children

Do not give VOMIDON TABLETS to infants and children who are under 12 years of age and weigh less than 35 kg.

Duration of treatment:

Must not exceed one week for treatment of nausea and vomiting. Up to four weeks for other indications. If treatment exceeds four weeks, the need for continued treatment to be reassessed.

If you have the impression that the effect of VOMIDON TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you have the impression that the effect of VOMIDON TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more VOMIDON TABLETS than you should**Signs and Symptoms**

If you have taken too much VOMIDON TABLETS you may experience agitation, altered state of awareness or trance, seizure, sleepiness, confusion, uncontrolled movements, such as irregular eye movements, or abnormal posture, such as twisted neck. See your doctor, especially if a child has taken the medicine.

It is important not take more VOMIDON TABLETS than you should. In the event of overdosage, patients should consult a doctor or pharmacist. If neither is available, they contact the nearest hospital or poison centre. Take along any tablets that are left, the container and the label so that the hospital staff can easily tell what medicine you have taken.

If you forget to take VOMIDON TABLETS

It is important to take your VOMIDON TABLETS regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking VOMIDON TABLETS

Take VOMIDON TABLETS for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

VOMIDON TABLETS can have side effects.

Not all side effects reported for VOMIDON TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VOMIDON TABLETS, please consult your health care provider for advice.

If any of the following happens, stop taking VOMIDON TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

Allergic reaction (urticarial) including:

- pruritus (severe itching of the skin).
- rash.
- sudden cardiac death, serious abnormal heart beats, sudden life-threatening severe allergic reaction, rapid swelling of the skin or mucosal tissues, convulsions in children

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VOMIDON TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequency unknown

Convulsions, Urinary retention, Continuous muscle spasms or contractions involving irregular jerky movements in children

These are all serious side effects. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- depression
- anxiety
- loss of interest in sex or diminished interest in sex
- headache
- somnolence
- restlessness
- diarrhoea
- rash
- itchiness
- enlarged or swollen breasts
- painful or tender breasts
- milk discharge from breasts or difficulty breast feeding
- irregular or stopped menstrual periods
- a general feeling of weakness
- dry mouth
- feeling dizzy

Less frequent side effects

- movements that you cannot control, such as muscle tremors, spasms or stiffness, feeling restless or difficulty sitting still, slow movement
- severe allergic reaction that may include:
 - a swollen face, lips, mouth, tongue or throat
 - difficulty swallowing or breathing
 - itchy rash (hives)
- palpitations
- seizures (fits)
- unexpected death resulting from an abrupt loss of heart function in a person who may or may not have known heart disease.

Other less frequent side effects include:

- hypersensitivity
- hives
- unusual discharge from breasts
- feeling agitated
- nervousness
- inability to urinate
- changes in certain laboratory test results

Inadvertent ingestion in children resulted in:

- movements that you cannot control, such as muscle tremors, spasms or stiffness, feeling restless or difficulty sitting still, slow movement.
- seizures
- feeling agitated

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> . By reporting side effects, you can help provide more information on the safety of VOMIDON TABLETS.

5. How to store VOMIDON TABLETS

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Store in the original package.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What VOMIDON TABLETS contains

The active substance is domperidone 10 mg per tablet.

The other ingredients are colour brilliant blue lake ci no.: 42090, gelatin, lactose, maize starch, magnesium stearate, purified water and sodium benzoate.

What VOMIDON TABLETS looks like and contents of the pack

What VOMIDON TABLETS looks like:

White to off-white coloured flavoured homogenous suspension.

Contents of the pack:

10 tablets in aluminium strip pack and 1 of these in one carton (i.e. 10 tablets per pack) or 10 of these strips in one carton (i.e. 100 tablets per pack). And 100 tablets in a securitainer.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road,

Stormill, Ext. 1,

Roodepoort,

1724

This leaflet was last revised in

31 October 2022

Registration numbers

31/5.7.2/0330 (South Africa)