

DOMPERIDONE VIATRIS

Domperidone (as maleate) Tablet 10 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Domperidone Viatris.

This leaflet answers some common questions about Domperidone Viatris.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Domperidone Viatris against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Domperidone Viatris is used for

Domperidone Viatris is used to treat

- nausea and vomiting
- discomfort caused by a slow moving stomach. Symptoms include not being able to finish a meal, a feeling of being "too full" or bloated after a meal, a loss of appetite, feeling sick and maybe vomiting or belching without relief.

This medicine belongs to a group of medicines called antiemetics and prokinetics. It works by blocking the action of a chemical messenger in the brain which causes the feeling of nausea and vomiting, as well as increasing the movement or contractions of the stomach and intestines, allowing food to move more easily through the stomach.

This medicine is unsuitable for use in adults and children weighing less than 35 kg.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

Before you take Domperidone Viatris

When you must not take it

Do not take Domperidone Viatris if you have an allergy to:

- any medicine containing domperidone
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Domperidone Viatris if you have or have had any of the following medical conditions:

- a tumour of the pituitary gland called prolactinoma
- you have or have had liver disease
- an increase in stomach or bowel contractions e.g. if you have had bleeding, a blockage or puncture in your gastrointestinal tract
- heart problems, including an abnormal heartbeat.

Do not take Domperidone Viatris if you take any of the following medications:

- ketoconazole, fluconazole, voriconazole, itraconazole or posaconazole which are used to treat fungal infections
- ritonavir or saquinavir used to treat HIV
- telaprevir used to treat hepatitis C
- erythromycin, clarithromycin or telithromycin antibiotics
- amiodarone, diltiazem or verapamil

Do not give this medicine to a child under the age of 2 years.

Safety and effectiveness in children younger than 2 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- pre-existing heart condition
- liver or kidney disease
- breast cancer
- lactose intolerance

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Domperidone Viatris.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Domperidone Viatris.

Some medicines may interfere with Domperidone Viatris. These include:

- disopyramide and quinidine used to treat irregular heart rate
- certain medicines used to treat heart conditions, e.g. diltiazem, verapamil, sotalol or amiodarone
- medicines such as haloperidol, pimozone, sertindole, citalopram, escitalopram, nefazodone, used for mood disorders
- antimalarial medicine such as halofantrine
- anticholinergic drugs, used to prevent travel sickness, treat Parkinson's Disease or relieve stomach cramps, muscular spasms
- dolasetron used to treat gastro intestinal issues
- amprenavir, atazanavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, used to treat HIV infections
- toremifene, vandetanib, medicine used in cancer
- aprepitant, used to treat nausea and vomiting
- methadone, used to treat chronic pain or opioid dependence
- antacids, ranitidine, cimetidine or omeprazole, used to neutralise or reduce the amount of stomach acid.

These medicines may be affected by Domperidone Viatris or may affect how well it works. You may

need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Domperidone Viatris

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much to take. This will depend on your condition and whether you are taking any other medicines.

The usual dose is one tablet taken three to four times a day.

How to take it

Domperidone is best taken 15 to 30 minutes before meals or food.

Swallow the tablets whole with a full glass of water.

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of Domperidone Viatris.

How long to take it

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

For nausea and vomiting, this medicine is usually used for a maximum of 1 week.

For other conditions, the initial duration of treatment is up to a maximum of 4 weeks.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Domperidone Viatris

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Domperidone Viatris.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Domperidone Viatris to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Domperidone Viatris affects you. This medicine may cause dizziness, tiredness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

- feeling anxious or nervousness,
- dizziness, sleepiness or drowsiness,
- fits or seizures,
- feeling agitated or irritable,
- dry mouth or thirst,
- stomach cramps, diarrhoea, constipation, nausea,
- rash or itchy skin.

The above list includes the more common side effects of your medicine.

They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- uncontrolled movements such as irregular eye movements, unusual movement of the tongue, abnormal posture such as twisted neck, trembling and muscle stiffness
- irregular or no menstrual period
- unusual secretion of breast milk or decrease in sex drive in men and women
- breast tenderness or breast enlargement in men and women.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fast or irregular heart beats
- difficulty passing urine or pain when passing urine
- signs of an allergic reaction such as rash or hives, swelling of the hands, feet, ankles, face, lips, tongue or throat, wheezing or difficulty breathing or swallowing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell

your doctor if you notice any other effects.

Some of these side effects for example, changes in liver function, can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Domperidone Viatris. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include agitation, altered consciousness, seizure, confusion, drowsiness, and uncontrolled movements.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Domperidone Viatris.

This medicine helps most people but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache,

After taking Domperidone Viatris

Storage

Keep your tablets in the pack until it is time to take it.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Domperidone Viatris or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Domperidone Viatris tablets are white round, biconvex, uncoated tablet with inscription "Dm 10" on one side.

Ingredients

Active ingredient:

Domperidone Viatris contains 10 mg of domperidone (as

domperidone maleate) as the active ingredient.

Inactive ingredients:

Domperidone Viatris also contains:

- lactose
- starch – maize
- cellulose – microcrystalline
- povidone
- sodium lauryl sulphate
- silica colloidal anhydrous
- magnesium stearate
- purified water.

Contains sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Domperidone Viatris is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

17 November 2022.
(Based on datasheet dated 10 May 2022)