

APO-Domperidone

Domperidone maleate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about domperidone. 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 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 your medicine.

You may want to read it again.

What this medicine used for

Domperidone is used to treat nausea, vomiting, and discomfort caused by a slow-moving stomach (known as gastroparesis). Symptoms include not being able to finish a meal, a feeling of being bloated after a meal, a loss of appetite, feeling sick, vomiting, or belching without relief.

How it works

Domperidone 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. It also works to increase the movement or

contractions of the stomach and intestines, allowing food to move more easily through the stomach.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Domperidone should not be used in children under the age of 18 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- 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, throat or other parts of the body
- rash, itching or hives on the skin:

Do not take this medicine 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 this medicine 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

There may be other medicines not listed above that should not be taken with domperidone.

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

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, plan to become pregnant or are breastfeeding or wishing to breastfeed

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.

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

Taking other medicines

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

Some medicines may interact with domperidone. Do not take domperidone if you are taking medicines that slow down the breaking down (metabolism) of other medicines in the body and can also affect your heart rhythm, these include:

- ketoconazole, fluconazole, itraconazole and voriconazole, used for treating fungal infections
- anticholinergic drugs, used to prevent travel sickness, gastrointestinal cramps, muscular spasms, or sleep disorders e.g. dextromethorphan or diphenhydramine

- dopaminergic agonists, used to treat Parkinson's Disease or digestive disorders
- clarithromycin, erythromycin and moxifloxacin, antibiotics used to treat certain bacterial infections
- amprenavir, atazanavir, fosamprenavir, indinavir, nelfinavir, ritonavir and saquinavir, used to treat HIV infections
- telaprevir which is a medicine for hepatitis C.
- certain medicines used to treat heart conditions e.g. diltiazem, verapamil, sotalol or amiodarone
- aprepitant, used to treat nausea and vomiting
- methadone, used to treat chronic pain or opioid dependence
- nefazodone, used for mood disorders
- antacids, ranitidine, cimetidine or omeprazole, used to neutralise or reduce the amount of stomach acid.

Do not take medicines that neutralize stomach acid or medicines that reduce the production of stomach acid within 2 hours of taking domperidone. This is because sufficient stomach acid is required to ensure that domperidone is properly absorbed by the body.

These medicines may be affected by this medicine 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.

Other medicines not listed above may also interact with domperidone.

How to take this medicine

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

They may differ to 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 of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

How to take it

Domperidone is best taken 15 to 30 minutes before meals and if necessary, at bedtime.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it for

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.

Make sure you have enough to last over weekends and holidays.

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 at the usual time.

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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much domperidone you may experience agitation, seizure, drowsiness, confusion and uncontrolled movements, such as irregular eye movements, or abnormal posture like a twisted neck.

While you are taking this medicine

Talk to your doctor if you have a pre-existing heart condition.

The risk of unusual heartbeat or sudden heart failure has been associated with domperidone use. The risk is higher in patients older than 60 years or taking more than three tablets daily. Domperidone should be used with caution and should be taken at the lowest effective dose, particularly in older patients. Treatment with domperidone should be stopped if signs or symptoms occur that may be associated with unusual heartbeat. Please talk to your doctor for advice.

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

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

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

Tell your doctor if you are going to have surgery, an anaesthetic or are going into hospital.

Keep all 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 give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

Side effects

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

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 side effects.

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

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

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

- headache, trouble sleeping, nervousness, depression, dizziness, tiredness or irritability
- sleepiness or drowsiness, fits or seizures, agitation
- dry mouth or thirst
- regurgitation, diarrhoea, constipation, nausea, changes in appetite or heartburn
- rash or itchy skin
- itchy eyes and crusty eyelids with discharge
- mouth ulcers or cold sores
- uncontrollable movements of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm
- irregular or no menstrual period
- unusual secretion of breast milk or decrease in sex drive in men or women
- breast tenderness or enlargement in men and women.
- Some of these effects will reverse on stopping treatment.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

- fast or irregular heart beats
- swelling of hands, ankles or feet
- passing urine more frequently or pain when passing urine
- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, skin rash, itching; swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (signs of an allergic reaction)

Tell your doctor or pharmacist if you notice any other side effects.

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

Storage and disposal

Storage

Keep your medicine in its pack until it is time to take it.

If you take your medicine out of its pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine 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 left over.

Product description

What it looks like

White round, biconvex uncoated tablets with inscription 'Dm 10' on one side.

Available in blisters of 25, 30 and 100 tablets. AUST R 242333.

*Not all pack sizes may be marketed.

Ingredients

Each tablet contains 10 mg of domperidone as the active ingredient.

It also contains the following:

- lactose monohydrate
- maize starch

- microcrystalline cellulose
- povidone
- sodium lauryl sulfate
- colloidal anhydrous silica
- magnesium stearate

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park, NSW 2113

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