

APO-Domperidone

Contains the active ingredient Domperidone (as maleate) 10 mg

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APO-Domperidone. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking APO-Domperidone the benefits this medicine is expected to have for you.

If you have any concerns about taking APO-Domperidone ask your doctor or pharmacist.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine used for

The name of your medicine is APO-Domperidone tablets. It contains the active ingredient Domperidone maleate.

It is used to treat the following conditions in adults: nausea and vomiting, discomfort caused by a slow moving stomach known as gastroparesis. 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed APO-Domperidone for another reason.

How it works

APO-Domperidone is an antiemetic and a prokinetic medicine. 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.

Before you take this medicine

When you must not take it

Do not take this medicine if:

You have or have had any of the following:

- a tumour of the pituitary gland called prolactinoma
- liver disease
- an increase in stomach or bowel contractions, for example, if you have had bleeding, a blockage or puncture in your gastrointestinal tract
- problems with your heart, including abnormal heart beat
- you are taking another medicine containing the active ingredient ketoconazole, coriconazole, itraconazole, posaconazole which is used to treat fungal infections
- you are taking another medicine containing the active ingredient ritonavir or siquinavir which is used to treat HIV
- you are taking another medicine containing the active ingredient telaprevir which is used to treat hepatitis C
- you are you are taking an antibiotic containing the active ingredient erythromycin, clarithromycin or telithromycin
- you are taking another medicine containing the active ingredient amiodarone, which is used to treat fast heart rate
- **you are hypersensitive to, or have had an allergic reaction to, domperidone or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, 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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency Department at the nearest hospital.

The expiry date (EXP) printed on the pack has passed.

The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - pre-existing heart condition
 - liver or kidney disease
 - breast cancer you are not able to digest lactose which is a sugar found in milk and milk products.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available

from your pharmacy, supermarket or health food shop.

Some medicines may interact with APO-Domperidone. These include:

- medicines for treating fungal infections, such as ketoconazole, fluconazole, itraconazole and voriconazole
- medicines that neutralise or reduce the amount of stomach acid (such as antacids, ranitidine, cimetidine, omeprazole)
- anticholinergic drugs (used to prevent travel sickness)
- dopaminergic agonists (used to treat Parkinson's Disease or digestive disorders)
- medicines used to treat HIV infections, such as amprenavir, atazanavir, fosamprenavir, indinavir, nelfinavir, ritonavir and saquinavir
- medicines used to treat high blood pressure or chest pain, such as diltiazem and verapamil
- amiodarone used to treat fast heart rate
- aprepitant used to treat nausea and vomiting
- an antidepressant called nefazodone
- medicines that neutralize or reduce the amount of stomach acid, such as antacids. Do not take medicines that neutralize stomach acid or medicines that reduce the production of stomach acid within 2 hours of taking APO-Domperidone. This is because sufficient stomach acid is required to ensure that APO-Domperidone is properly absorbed by the body.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with domperidone.

How to take this medicine

Follow carefully all directions given to you by your doctor.

Their instructions may be different to the information in this leaflet.

If you do not understand the instructions on the box/bottle, 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.

Adults:

The usual dose in adults is one tablet three times a day.

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

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

How to take it

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

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and 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.

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 missed dose 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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia or 0800 POISON [or 0800 764 766] in New Zealand) for advice. Alternatively, go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking this medicine

The risk of unusual heart beat 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. APO-Domperidone should be used with caution and should be taken at the lowest effective dose, particularly in older patients. Talk to your doctor if you have a pre-existing heart condition.

Treatment with APO-Domperidone should be stopped if signs or symptoms occur that may be

associated with unusual heart beat, please talk to your doctor for advice.

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Things you must not do

Do not:

- give this medicine to anyone else, even if their symptoms seem similar to yours
- take your medicine to treat any other condition unless your doctor tells you to
- stop taking your medicine, or change the dosage, without first checking with your doctor.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking domperidone or if you have any questions or concerns.

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.

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- headache, trouble sleeping, nervousness, 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
- 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 breast enlargement in men.

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.

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

Allergic reactions

If you think you are having an allergic reaction to domperidone, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, skin rash, itching
- shortness of breath

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

Other side effects not listed above may occur in some people. Tell your doctor if you notice any other effects.

Storage and disposal

Storage

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

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

Keep your medicine in a cool dry place where the temperature will stay 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 window sill 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 it has passed its expiry date, your pharmacist can dispose of the remaining w medicine safely.

Product description

What APO-Domperidone tablets looks like

Tablets are white round, biconvex uncoated tablets with inscription 'Dm 10' on one side.

They are available in blisters in cartons of 25, 30 and 100 tablets.

*Not all pack sizes may be marketed.

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Ingredients

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

It also contains the following inactive ingredients:

- Lactose
- Maize starch
- Microcrystalline cellulose
- Povidone
- Sodium lauryl sulfate
- Colloidal anhydrous silica
- Magnesium stearate.

Australian Registration Numbers

APO-Domperidone 10 mg tablets
(Blister Pack): AUST R 242333.

Sponsor

Apotex Pty Ltd
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This leaflet was last updated in July 2016.