

APO-DOMPERIDONE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-DOMPERIDONE?

APO-DOMPERIDONE contains the active ingredient domperidone. APO-DOMPERIDONE is used to treat the following condition 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.

For more information, see Section [1. Why am I using APO-DOMPERIDONE?](#) in the full CMI.

2. What should I know before I use APO-DOMPERIDONE?

Do not use if you have ever had an allergic reaction to APO-DOMPERIDONE or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use APO-DOMPERIDONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-DOMPERIDONE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-DOMPERIDONE ?

- 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.

More instructions can be found in Section [4. How do I use APO-DOMPERIDONE?](#) in the full CMI.

5. What should I know while using APO-DOMPERIDONE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using APO-DOMPERIDONE
Things you should not do	• Do not use APO-DOMPERIDONE if you have a tumour of the pituitary gland called prolactinoma, have or have had liver disease, an increase in stomach or bowel contractions, have problems with your heart including an abnormal heart beat or are taking one of the medicines listed in section 2 in the full CMI.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how APO-DOMPERIDONE affects you.
Drinking alcohol	• Tell your Doctor if you drink alcohol.
Looking after your medicine	• Keep APO-DOMPERIDONE tablets in the pack until it is time to take them • Keep APO-DOMPERIDONE tablets in a cool dry place where the temperature is below 30°C.

For more information, see Section [5. What should I know while using APO-DOMPERIDONE?](#) in the full CMI.

6. Are there any side effects?

A risk of unusual heart beat or sudden heart failure has been associated with APO-DOMPERIDONE use. The risk is higher in patients older than 60 years or taking more than three tablets daily. Tell your doctor if you have heart disease, or if you experience an allergic reaction to this medicine.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-DOMPERIDONE

Active ingredient: *Domperidone maleate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-DOMPERIDONE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-DOMPERIDONE.**

Where to find information in this leaflet:

- [1. Why am I using APO-DOMPERIDONE?](#)
- [2. What should I know before I use APO-DOMPERIDONE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-DOMPERIDONE?](#)
- [5. What should I know while using APO-DOMPERIDONE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-DOMPERIDONE?

APO-DOMPERIDONE contains the active ingredient domperidone.

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.

APO-DOMPERIDONE is used to treat

- nausea and vomiting
- discomfort caused by a slow-moving stomach known as gastroparesis.

2. What should I know before I use APO-DOMPERIDONE?

Warnings

Do not use APO-DOMPERIDONE if:

- you are allergic to domperidone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have a tumour of the pituitary gland called prolactinoma
- you have or have had liver disease
- an increase in stomach or bowel contractions, for example, if you have had bleeding, a blockage or puncture in your gastrointestinal tract
- you have problems with your heart, including abnormal heart beat

- you are taking another medicine containing the active ingredient ketoconazole, voriconazole, itraconazole, posaconazole which is used to treat fungal infections
- you are taking another medicine containing the active ingredient ritonavir or saquinavir 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 taking an antibiotic containing the active ingredient erythromycin, clarithromycin or telithromycin.

Check with your doctor if you:

- have a pre-existing heart condition
- have or have ever had a kidney disease
- have or have ever had breast cancer
- are not able to digest lactose which is a sugar found in milk and milk products.
- If symptoms persist, worsen, or if new symptoms appear, stop use and see your doctor.

APO-DOMPERIDONE should not be used in children.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with APO-DOMPERIDONE and affect how it works.

Medicines that slowing down the breaking down (metabolism) of other medicines in the body and can also affect your heart rhythm such as:

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

In particular, tell your doctor or pharmacist if you are taking any of the following:

- medicines for treating fungal infections, such as ketoconazole, fluconazole, itraconazole and voriconazole
- anticholinergic drugs (medicines to treat allergy, asthma, incontinence, gastrointestinal cramps, muscular spasms, depression or sleep disorders, for example, dextromethorphan or diphenhydramine)
- dopaminergic agonists (used to treat Parkinson's Disease or digestive disorders)
- an antibiotic, such as clarithromycin, telithromycin and erythromycin
- 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 neutralise or reduce the amount of stomach acid, such as antacids. Do not take medicines that neutralise stomach acid or medicines that reduce the production of stomach acid within 2 hours of taking APO-DOMPERIDONE. Antacids/ acid reducers should be taken after meals. This is because sufficient stomach acid is required to ensure that APO-DOMPERIDONE is properly absorbed by the body.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-DOMPERIDONE .

4. How do I use APO-DOMPERIDONE?

How much to take / use

- 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.

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

- Follow the instructions provided and use APO-DOMPERIDONE until your doctor tells you to stop.

When to take / use APO-DOMPERIDONE

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

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you forget to use APO-DOMPERIDONE

- Try to take each dose at the scheduled time.
- The missed dose should be omitted and the actual dosing schedule resumed. If it is almost time for

your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you use too much APO-DOMPERIDONE

If you think that you have used too much APO-DOMPERIDONE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using APO-DOMPERIDONE?

Things you should do

The risk of unusual heart beat or sudden heart failure has been associated with APO-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 heartbeat, please talk to your doctor for advice.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-DOMPERIDONE affects you.

Use caution when driving a motor vehicle or operating machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep APO-DOMPERIDONE tablets in the pack until it is time to take them.
- Keep APO-DOMPERIDONE tablets in a cool dry place where the temperature is below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Tell your doctor if you experience any of the following side effects	What to do
- headache, trouble sleeping, nervousness, depression, dizziness, tiredness or irritability - sleepiness or drowsiness, 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 - Blood test showing abnormal, liver enzymes - Cholesterol, prolactin hormone - 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 and women. These effects will reverse on stopping treatment.	Speak to your doctor if you experience any of these side effects

Serious side effects	What to do
- fast or irregular heart beats - swelling of hands, ankles or feet - passing urine more frequent or pain when passing urine. - fits or seizures - unable to pass urine	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

- uncontrollable movements of the face or arms and legs - excessive trembling - excessive muscle stiffness - muscle spasm	
you have an allergic reaction to APO-DOMPERIDONE (allergy can be recognised, for instance, by skin rash, itching, shortness of breath and/or swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing)	STOP using APO-DOMPERIDONE and tell your doctor immediately if you have an allergic reaction.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-DOMPERIDONE contains

Active ingredient (main ingredient)	10 mg of domperidone as the active ingredient.
Other ingredients (inactive ingredients)	- lactose monohydrate - maize starch - microcrystalline cellulose - povidone - sodium lauryl sulfate - colloidal anhydrous silica - magnesium stearate
Potential allergens	contains sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

This medicine is gluten-free.

What APO-DOMPERIDONE 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.

Who distributes APO-DOMPERIDONE

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel St,
Cremorne VIC 3121
www.arrotex.com.au

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