

APO-Duloxetine

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-Duloxetine?

APO-Duloxetine contains the active ingredient duloxetine hydrochloride. APO-Duloxetine is used to treat major depressive disorder (MDD) and generalized anxiety disorder (GAD)-excessive worry.

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

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

Do not use if you have ever had an allergic reaction to Duloxetine hydrochloride 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-Duloxetine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Duloxetine 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-Duloxetine?

- Your doctor will tell you how much APO-Duloxetine you need to take each day.
- Swallow the capsule whole with a full glass of water. It may be taken with or without meals.

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

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

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-Duloxetine• If you are going to have surgery, tell the surgeon or anesthetist that you are taking APO-Duloxetine.• If you become pregnant while taking APO-Duloxetine, tell your doctor immediately.• Tell your doctor immediately if you have any suicidal thoughts or other mental/ mood changes
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine or lower the dosage without checking with your doctor.• Do not take APO-Duloxetine 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 'binge drink' or drink alcohol excessively during treatment with APO-Duloxetine.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate any machinery until you know how APO-Duloxetine affects you• APO-Duloxetine may impair your judgement, affect your thinking or motor skills.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol. Large amounts during treatment can cause severe liver injury.• APO-Duloxetine may impair your judgement, affect your thinking or motor skills.
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in the pack until it is time to take them.• Keep your capsules in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Common side effects include fatigue, weakness, diarrhoea, chills, headache, nausea, vomiting, weight loss, dry mouth, trouble sleeping, anxiety, abnormal thoughts/dreams, drowsiness, dizziness, sweating, twitches, rash, itch, sexual disturbances, frequent urination, changes in taste and changes in vision. Serious side effects may include: serious allergic reactions, muscle spasms, tremors, seizures, fast, irregular heartbeat, abnormal bleeding, sudden mood swings, confusion, liver problems, loss of coordination, serotonin syndrome and stress cardiomyopathy

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-Duloxetine

Active ingredient(s): *Duloxetine (as duloxetine hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Duloxetine. **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-Duloxetine.**

Where to find information in this leaflet:

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

1. Why am I using APO-Duloxetine?

APO-Duloxetine contains the active ingredient duloxetine hydrochloride. APO-Duloxetine belongs to a group of medicines called serotonin and noradrenaline reuptake inhibitors (SNRIs). SNRIs are believed to work by their actions on serotonin and noradrenaline in the brain. Serotonin and noradrenaline are the chemical messengers responsible for controlling the psychological and painful symptoms of depression

APO-Duloxetine is used to treat:

- Major depressive disorder (MDD)
- Generalized anxiety disorder (GAD) - excessive worry.

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

Warnings

Do not use APO-Duloxetine if:

- you are allergic to duloxetine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of the 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.

Check with your doctor if you:

- have any other medical conditions, such as:
 - high pressure in the eye (glaucoma)
 - high blood pressure as your doctor may monitor your blood pressure.
 - Heart conditions
 - Kidney problems as you may need to take a Lower dose of APO-Duloxetine
 - Fits (seizures)
 - Mania
 - Bipolar disorder
 - Bleeding or clotting disorders
 - Diabetes
- take any medicine for any other condition.
- have allergies to any other medicines, foods, preservatives or dyes.
- drink alcohol. Talk to your doctor about how much alcohol you drink.

Do not take this medicine if you have or have had liver disease.

Do not take this medicine if you are taking any medicine called a monoamine oxidase inhibitor (MAOI) (including moclobemide which is a reversible MAOI (RIMA)) or have been taking a MAOI within the last 14 days. Check with your doctor or pharmacist if you are unsure as to whether you are taking a MAOI.

If you take Duloxetine while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever, rapid pulse, rapid breathing or confusion.

Do not take this medicine if you are taking a medicine that is a potent inhibitor of CYP1A2, such as fluvoxamine or ciprofloxacin.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for 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 and duloxetine may interfere with each other. These include:

- Monoamine oxidase inhibitor (MAOI), used to treat some types of depression.
You must stop taking MAOIs at least two weeks before starting duloxetine.
You must stop taking Duloxetine at least 5 days before you start taking a MAOI.
- Other medicines used to treat depression, panic disorder, anxiety, or obsessive illness, including tryptophan.
- Strong painkillers such as tramadol or pethidine.
- A type of migraine treatment called ‘triptans’ such as sumatriptan or zolmitriptan.
- Medicines used to treat stress urinary incontinence such as tolterodine.
- Medicine used to treat heart problems such as flecainide or propafenone.
- Thioridazine, used to treat schizophrenia
- Herbal medicines such as St John’s Wort (*Hypericum perforatum*).
- Warfarin, used to thin the blood (anticoagulant) or other medicines known to affect blood coagulations (NSAIDs or aspirin).

These medicines may be affected by duloxetine 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.

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-Duloxetine.

4. How do I use APO-Duloxetine?

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.

For major depressive disorder

The recommended dose is usually one 60mg capsule once daily.

For generalised anxiety disorder

The recommended dose is 30mg to 120mg, taken once daily.

You may be started on a lower dose to help reduce side effects. If you have severe kidney disease, the recommended starting dose is one 30mg capsule once daily.

When to take APO-Duloxetine

- Take your medicine at about 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.
- It does not matter if you take this medicine before or after food.

How to take APO-Duloxetine

- Swallow the capsule whole with a full glass of water.
- Do not open the capsules and crush the pellets inside because the medicine may not work as well.

How long to take APO-Duloxetine for

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

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

The length of treatment with duloxetine will depend on how quickly your symptoms improve. Most medicines of this type take time to work so don’t be discouraged if you do not feel better right away.

Although you may notice an improvement, 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 use APO-Duloxetine

APO-Duloxetine should be used regularly at the same time each day.

If it is almost time for 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 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.

If you use too much APO-Duloxetine

If you think that you have used too much APO-Duloxetine, 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.

Symptoms of an overdose may include drowsiness, convulsions and vomiting. They may also include feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, muscle jerks, or fast heartbeat.

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

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

Things you should do

Call your doctor straight away if you:

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 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 or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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.

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. These symptoms may continue or get worse during the first one or two months

of treatment, until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in young adults under 25 years of age.

All mention of suicide or violence must be taken seriously. Contact your doctor or a mental health professional right away or go to the nearest hospital for treatment if you or someone you know is showing any of the following warning signs of suicide:

- worsening of your depression
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood

If you notice any of the following, contact your doctor immediately:

itchy skin

dark urine

yellowing of the skin or eyes

tenderness over the liver

symptoms of the 'flu'

These could be signs of liver damage. Your doctor may do some blood tests to check your liver or tell you to stop taking your medicine.

Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using APO-Duloxetine.

Things you should not do

Do not take this medicine 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.

If you stop taking it suddenly, your condition may worsen, or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Driving or using machines

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

APO-Duloxetine may cause dizziness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may cause dizziness or drowsiness in some people. You should avoid 'binge drinking' or drinking excessively during treatment with duloxetine as it can cause severe liver injury.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

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 25°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 windowsills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

When to discard your medicine

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.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • dry mouth, mouth ulcers, thirst or bad taste • burping or belching, indigestion, stomach pain, nausea, vomiting 	<p>Speak to your doctor if you have any of</p>

<ul style="list-style-type: none"> • difficulty swallowing • constipation, diarrhoea or wind (flatulence) • bad breath • loss of appetite or weight loss • headache • trouble sleeping • dream abnormalities • drowsiness • feeling tired or having no energy • dizziness • tremor • blurred vision • feeling anxious, agitated or restless • confusion and attention problems • tingling and numbness of hands, face, mouth and feet • yawning or throat tightness • sexual problems • pain in testicles • difficulty urinating (passing water), urinating frequently or needing to urinate at night • irregular heart beat • hot and cold sweats • flushing • skin rash • tendency to bruise • sore ears or sore throat • ringing in ears • muscle pain, stiffness or twitching • walking problems • restless legs 	<p>these less serious side effects and they worry you.</p>
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • signs of a possible liver problem such as nausea, vomiting, loss of appetite, itchy skin, dark urine, yellowing of the skin or eyes, tenderness over the liver or symptoms of the 'flu' • high pressure in the eye (glaucoma) • feeling tired, weak or confused and having aching, stiff or uncoordinated muscles. • This may be because you have low sodium levels in the blood (hyponatremia or syndrome of inappropriate antidiuretic hormone) • abdominal pain, traces of blood in your stools, or if your stools 	<p>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.</p>

<p>are dark in color.</p> <ul style="list-style-type: none"> • This may be because you have increased bleeding, possibly in the gastric tract (gastrointestinal bleeding). You may also feel weakness, dizziness and experience nausea and/or vomiting • seeing or hearing things (hallucinations) • dizziness or fainting when you stand up, especially from a lying or sitting position • uncontrollable movements • if you have some or all of the following symptoms you may have something called serotonin syndrome: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heart beat • stiff neck or jaw muscles (lockjaw) • fits or seizures • mood of excitement, over-activity and uninhibited behavior • aggression or anger especially after starting or stopping taking this medicine <p>Some of these side effects can only be found when your doctor does tests from time to time to check your progress. These include:</p> <ul style="list-style-type: none"> • increased blood pressure • heart rhythm changes • underactive thyroid gland • liver function changes 	
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Serious side effects

Serious side effects	What to do
<p>Some of these side effects can only be found when your doctor does tests from time to time to check your progress. These include:</p> <ul style="list-style-type: none"> • increased blood pressure • heart rhythm changes • underactive thyroid gland • liver function changes <p>symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body;</p>	<p>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.</p>

rash, itching or hives on the skin	
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The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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-Duloxetine contains

Active ingredient (main ingredient)	Duloxetine Hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Sugar Spheres (ARTG ID 2535) • ascorbic acid • hypromellose • purified talc • purified water • sucrose • hypromellose phthalate • triethyl citrate • gelatin • titanium dioxide • brilliant blue FCF • iron oxide yellow (60 mg capsule only) • Tekprint SB-4020 Green Ink (ARTG ID 2652; 30 mg capsule only) • TekPrint SW-0012 White Ink (ARTG ID 13175; 60 mg capsule only).
Potential allergens	N/A

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

This medicine is gluten-free, lactose-free, tartrazine-free and free of other azo dyes.

This medicine may contain traces of sulfites.

What APO-Duloxetine looks like

30 mg capsules

Hard gelatin capsules with white opaque body and blue opaque cap, imprinted "157" on the body and "A" on the cap in green ink. Filled with white to off-white granules. AUST R 427036.

60 mg capsules

Hard gelatin capsules with green opaque body and blue opaque cap, imprinted "158" on the body and "A" on the cap in white ink. Filled with white to off-white granules. AUST R 427037.

Available in blister packs of 28 capsules.

* Not all strengths may be available.

Who distributes APO-Duloxetine

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121
www.arrotex.com.au

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