

APO-Duloxetine

Contains the active ingredient duloxetine (as duloxetine hydrochloride)

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 duloxetine. 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 using this medicine against the benefits they expect it will have for you.

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 is used for

The name of your medicine is APO-Duloxetine. It contains the active ingredient duloxetine hydrochloride.

It is used to treat:

- major depressive disorder (MDD)
- generalised anxiety disorder (GAD) - excessive worry.

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

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

How it works

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

Use in children

This medicine should not be used in children and adolescents 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 or have had liver disease.**
- **You are taking a 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 you are unsure whether or not you are taking a MAOI.
- **You are taking a medicine that is a potent inhibitor of CYP1A2, such as fluvoxamine or ciprofloxacin.**
Check with your doctor if you are unsure whether or not you are taking a potent inhibitor of CYP1A2.
- **You are hypersensitive to, or have had an allergic reaction to, duloxetine 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 hayfever-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:
 - glaucoma (an eye disease where the fluid pressure in the eye may be high)
 - high blood pressure
 - heart problems
 - kidney problems
 - history of fits (seizures)
 - diabetes.
3. You, or members of your family, have experienced bipolar disorder, depression or suicide.
4. 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.
5. You are currently breast-feeding or you plan to breast-feed.
Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.

8. You drink alcohol.
People who drink excessive amounts of alcohol should not take duloxetine. Drinking too much alcohol could increase the risk of liver problems during treatment with duloxetine.
9. 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 duloxetine. These include:

- monoamine oxidase inhibitors (MAOIs), medicines 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 illnesses, including tryptophan
- strong painkillers such as tramadol, pethidine
- a type of migraine treatment called 'triptans', such as sumatriptan or zolmitriptan
- medicines used to treat stress urinary incontinence such as tolteridone
- medicines used to treat heart problems such as flecainide or propafenone
- thioridazine, a medicine used to treat schizophrenia
- herbal medicines such as St John's Wort (*Hypericum perforatum*)
- warfarin, a medicine used to thin the blood (anticoagulant).

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 duloxetine.

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.

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.

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

For major depressive disorder, the recommended dose is usually one 60 mg capsule once daily.

For generalised anxiety disorder, the recommended dose is 30 mg to 120 mg, 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 30 mg capsule once daily.

How to take it

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. Duloxetine may be taken with or without meals.

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.

It does not matter if you take it before, with or after food.

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) 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.

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.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if you:

- are about to be started on any new medicine
- are pregnant or are planning to become pregnant
- are breast-feeding or are planning to breast-feed
- are about to have any blood tests

- are going to have surgery or an anaesthetic or are going into hospital.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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 occasionally do tests to make sure the medicine is working and to prevent side effects.

Visit your doctor regularly for a check-up.

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.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you. It may cause dizziness or drowsiness.

Be careful when drinking alcohol while you are taking this medicine.

You should avoid 'binge drinking' or drinking excessively during treatment with duloxetine as it can cause severe liver injury.

Drinking alcohol with duloxetine may also 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.

Possible side effects

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

Do not be alarmed by the following lists of 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 or pharmacist if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild:

- dry mouth, mouth ulcers, thirst, bad taste
- burping or belching, indigestion, stomach pain, nausea, vomiting

- difficulty swallowing
- constipation, diarrhoea, wind (flatulence)
- bad breath
- loss of appetite, 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, sore throat
- ringing in ears
- muscle pain, stiffness or twitching
- walking problems
- restless legs.

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

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- **signs of a possible liver problem** such as itchy skin, dark urine, yellowing of the skin or eyes, tenderness over the liver, 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 (hyponatraemia or syndrome of inappropriate antidiuretic hormone)

- abdominal pain, traces of blood in your stools, or if your stools are dark in colour. 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 behaviour
- aggression or anger especially after starting or stopping taking this medicine.

Other changes you may not be aware of:

- increased blood pressure
- heart rhythm changes
- underactive thyroid gland
- liver function changes.

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

Allergic reactions

If you think you are having an allergic reaction to duloxetine, 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, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms.

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 25°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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

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.

Blister packs of 28 capsules.

- 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. Blister packs of 28 capsules.

APO-Duloxetine is available in*:

30 mg:

- Blister packs of 28

60 mg:

- Blister packs of 28

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each capsule contains 30 mg or 60 mg of duloxetine (as hydrochloride) as the active ingredient.

It also contains the following inactive ingredients:

- Sugar Spheres (ARTG ID 2535)
- 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).

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

Australian Registration Numbers

APO-Duloxetine 30 mg blister pack:
AUST R 217985.

APO-Duloxetine 60 mg blister pack:
AUST R 217986.

Sponsor

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