

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

This leaflet answers some common questions about this medicine. 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 this medicine 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 the medicine.

You may need to read it again.

What this medicine is used for

Duloxetine is used to treat:

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

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.

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.

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 an allergy to:

- any medicine containing duloxetine
- 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 or other parts of the body
- rash, itching or hives on the skin

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 or not 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.

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:

- 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
- you, or members of your family, have experienced bipolar disorder, depression or suicide

If you have high blood pressure or heart problems your doctor may monitor your blood pressure.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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

If duloxetine is taken during pregnancy, you should be careful, particularly at the end of pregnancy. Transitory withdrawal symptoms have been reported rarely in the newborn after maternal use in the last 3 months of pregnancy.

Tell your doctor if you are breastfeeding or plan to breastfeed.

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

Duloxetine passes into breast milk and there is a possibility that your baby may be affected.

Tell your doctor if 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.

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 or 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 and duloxetine may interfere with each other. 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 or pethidine

- a type of migraine treatment called 'triptans', such as sumatriptan or zolmitriptan
- medicines used to treat stress urinary incontinence such as tolterodine
- medicines 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 coagulation (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.

How to take this medicine

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

They may differ from the information contained in this leaflet.

If you do not understand the directions, 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.

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.

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.

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.

It does not matter if you take this medicine before or after food.

How long to take it 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 take it

If it is almost time to take 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 that 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 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 the 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.

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

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.

Things you must 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

Be careful when driving or operating machinery until you know how this medicine affects you.

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.

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.

Side effects

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

All medicines can have side effects. Sometimes they are serious but most of the time they are not. If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of 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 and they worry you:

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

The above list includes the more common side effects. Mostly, these are mild.

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

- **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 (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

The above list includes serious side effects. You may need medical attention. Most of these side effects are rare.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress. These include:

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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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; rash, itching or hives on the skin

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 that is making you feel unwell.

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

- 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.

This medicine may contain traces of sulfites.

Sponsor

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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 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.

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. AUST R 217985.

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 217986

Available in blister packs of 28 capsules.

* Not all strengths 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