

DULOXECOR

(duloxetine hydrochloride)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DULOXECOR. 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 DULOXECOR 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 DULOXECOR is used for

DULOXECOR is used to treat major depressive disorder (depression), Diabetic Peripheral Neuropathic Pain (nerve pain caused by diabetes) and Generalised Anxiety Disorder (excessive worry)

DULOXECOR 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 physical 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 it for another reason.

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

DULOXECOR is not recommended for use in children and adolescents under the age of 18 years.

Before you take DULOXECOR

When you must not take it

Do not take DULOXECOR if you have an allergy to:

- any medicine containing duloxetine hydrochloride;
- 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 DULOXECOR if you have liver disease.

This could increase the chance of you having liver problems during treatment with DULOXECOR.

Do not take this medicine if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) 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 do take DULOXECOR while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever,

rapid pulse, rapid breathing and mental state from extreme agitation progressing to confusion and coma (a condition called serotonin syndrome).

Do not take DULOXECOR if you are taking another medicine that strongly interferes with how the liver works (potent CYP1A2 inhibitor). For example, another medicine for depression called fluvoxamine. Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a potent CYP1A2 inhibitor.

Do not take DULOXECOR with thioridazine, a medicine used to treat schizophrenia.

Do not take DULOXECOR if you are taking another medicine for depression called fluvoxamine.

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 medical conditions, especially if you have:

- a condition in which the pressure of fluid in the eye may be high (glaucoma)
- high blood pressure
- heart problems

- kidney problems as you may need to take a lower dose of DULOXECOR
- history of fits (seizures)
- bipolar disorder
- bleeding/clotting disorders
- diabetes

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.

DULOXECOR should only be used in pregnancy if the potential benefits outweigh the potential risks.

Your doctor can discuss with you the risks and benefits involved.

When taken in the last 3 months of pregnancy, DULOXECOR may affect your newborn baby. They may experience symptoms such as irritability, constant crying, feeding difficulties, vomiting, fluctuating temperature, seizures, tremors, jitteriness, bluish appearance (cyanosis), breathing interruptions, wheezing or shallow breathing, low blood sugar, muscle stiffness, muscle weakness, or overresponsive reflexes. These symptoms are uncommon and may be due to the effect of DULOXECOR or the discontinuation of DULOXECOR.

These symptoms usually begin immediately after the baby is born, or within a few days of birth, and should only last for a short time. If this happens to your baby, you should contact your doctor and/or midwife immediately.

Taking DULOXECOR during pregnancy may increase the risk of pre-term birth. If you take DULOXECOR near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth. Tell your doctor or midwife if you are taking DULOXECOR so that they can advise you.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Breastfeeding while on DULOXECOR is not recommended.

Talk to your doctor about how much alcohol you drink. People who drink excessive amounts of alcohol should not take DULOXECOR.

Drinking too much alcohol could increase the chance of you having liver problems during treatment with DULOXECOR.

If you have not told your doctor about any of the above, tell them before you start taking DULOXECOR.

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 DULOXECOR may interfere with each other. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression.
You should stop taking MAOIs at least two weeks before starting DULOXECOR.
You must stop taking DULOXECOR 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
- tricyclic antidepressants such as nortriptyline, imipramine, and desipramine

- medicines used to treat heart problems such as flecainide or propafenone
- phenothiazines such as chlorpromazine and prochlorperazine, used to treat schizophrenia/mood disorders and nausea
- SSRIs used to treat depression (e.g. paroxetine, escitalopram, sertraline)
- Other SNRIs used to treat depression (e.g. venlafaxine, desvenlafaxine)
- medicines used to treat blood pressure
- medications to pass urine (diuretics)
- herbal medicines such as St John's Wort (*Hypericum perforatum*)
- warfarin, a medicine used to thin the blood (anticoagulant) or other medicines known to affect blood coagulation (NSAIDs, aspirin)
- antacids or medicines for indigestion

Do not start to take any other medicine unless prescribed or approved by your doctor.

These medicines may be affected by DULOXECOR 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 DULOXECOR

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 instructions on the carton, ask

your doctor or pharmacist for help.

How much to take

The usual recommended dose of DULOXECOR in Major Depressive Disorder or Diabetic Peripheral Neuropathic Pain is one 60 mg capsule taken once daily.

The recommended dose of DULOXECOR in Generalised Anxiety Disorder is between 30 mg and 120 mg, taken once daily.

Your doctor may start you on a lower dose to help reduce side effects.

If you have severe kidney disease, the recommended starting dose of DULOXECOR is one 30 mg capsule taken 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.

DULOXECOR may be taken with or without meals.

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.

How long to take it

The length of treatment with DULOXECOR 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.

If you forget to take it

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 that you missed.

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 DULOXECOR.

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. Symptoms may also include some or all of the following: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, muscle jerks, fast heart beat.

While you are taking DULOXECOR

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DULOXECOR.

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. If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of 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.

Suicidal thoughts or other mental/mood changes may also worsen when the dose of DULOXECOR is increased or decreased.

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.

All mentions of suicide or violence must be taken seriously.

If you notice any of the following contact your doctor right away.

Your doctor may do some blood tests to check your liver or tell you to stop taking your medicine. Signs of liver problems include:

- itchy skin
- dark urine
- yellowing of the skin or eyes
- tenderness over the liver
- symptoms of the 'flu'

These may be signs of serious liver damage.

Things you must not do

Do not take DULOXECOR 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 DULOXECOR 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 like dizziness, nausea, headache, tingling or numbness, fatigue, vomiting, irritability, nightmares, difficulty sleeping, diarrhoea, anxiety, excessive sweating, drowsiness imbalance, and muscle pain. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

DULOXECOR may cause dizziness or drowsiness in some people. It may also impair your judgment, affect your thinking or motor skills.

Do not drive or operate machinery until you know how DULOXECOR affects you.

Do not let yourself run out of DULOXECOR over the weekend or on holidays.

Things to be careful of

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

Drinking large amounts of alcohol during treatment with

DULOXECOR can cause severe liver injury.

You should avoid 'binge drinking' or drinking excessively during treatment with DULOXECOR.

Drinking alcohol with this medicine may also cause dizziness or drowsiness in some people. If you have any of these symptoms, do not drive, use 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 DULOXECOR.

This medicine helps many people with depression, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the 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.

The following side effects are the more common side effects of DULOXECOR and are often mild and short-lived.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dry mouth, mouth ulcers, thirst, bad taste
- burping or belching, indigestion, stomach pain, nausea, vomiting,
- constipation, diarrhoea, wind (flatulence)
- bad breath
- loss of appetite, weight loss
- headache
- trouble sleeping
- abnormal dreams (including nightmares)
- drowsiness

- feeling tired or having no energy
- sexual disturbances (decreased sexual drive, problems with orgasm, ejaculation, or erection)
- dizziness
- tremor
- blurred vision, dry eye, dilated pupils
- feeling anxious, agitated or restless
- tingling and numbness of hands, face, mouth and feet
- yawning
- throat tightness, difficulty swallowing
- difficulty urinating (passing water), urinating frequently or needing to urinate at night.
- irregular heart beat
- excessive sweating
- hot and cold sweats, fever, chills
- sore throat, cough
- ringing in ears, ear pain
- muscle pain, stiffness or twitching
- Changes to the way you walk
- flushing
- skin rash
- restless legs

These are the more common side effects of your medicine.

Tell your doctor immediately if you notice any of the following:

- **signs of a possible serious liver problem, such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and/or eyes, dark urine**
- 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
- stiff neck
- clenching or grinding teeth
- mood of excitement, over-activity and uninhibited behaviour.
- confusion and attention problems aggression or anger especially after starting or stopping taking this medicine

You may need urgent medical attention.

Other changes you may not be aware of:

- increased blood pressure
- heart rhythm changes
- underactive thyroid gland
- liver function changes
- high pressure in the eye (glaucoma)

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

- itching, skin rash or hives
- shortness of breath, wheezing or trouble breathing
- swelling of the face, lips, tongue or other parts of the body
- fits or seizures
- feeling tired, dizziness, nausea, vomiting, sleepy, weak or confused and having aches, stiff or uncoordinated muscles, fainting, falls and seizures. This may be because you have low sodium levels in the blood (hyponatraemia or syndrome of inappropriate antidiuretic hormone). Elderly and dehydrated patients are at increased risk.
- if you have some or all of the following symptoms you may have something called serotonin syndrome: feeling confused, feeling restless, agitation, mood swings, sweating, shaking, diarrhoea, shivering, tremor, loss of coordination, overactive

reflexes, hallucinations, sudden jerks in your muscles or a fast heart beat.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

After taking DULOXECOR

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep as well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store DULOXECOR 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 it 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 it looks like

DULOXECOR 30 mg capsules have an opaque blue color cap and

opaque white color body, imprinted “Dulox” on cap with white ink and “30 mg” on body with black ink and are available in packs of 28 capsules in blister.

DULOXECOR 60 mg capsules have an opaque blue color cap and opaque green color body, imprinted “Dulox” on cap with white ink and “60mg” on body with white ink and are available in packs of 28 capsules in blister.

Ingredients

Active Ingredients

- 30 mg capsule - duloxetine hydrochloride equivalent to duloxetine 30 mg
- 60 mg capsule - duloxetine hydrochloride equivalent to duloxetine 60 mg

Inactive Ingredients

- sugar spheres
- hypromellose
- hydroxypropylcellulose
- crospovidone
- talc-purified
- triethyl citrate
- titanium dioxide
- hypromellose phthalate
- gelatin
- sodium lauryl sulphate
- indigo carmine
- TEK SW 0012 –white ink (ARTG No.13175)
- TEK SW 9008 –black ink (ARTG No.2328) (30 mg capsule)
- iron oxide yellow (60 mg capsule).

This medicine does not contain lactose, gluten, tartrazine or any other azo dyes.

Name and Address of Sponsor

Pharmacor Pty Ltd.
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The Zenith,
821 Pacific Highway,
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60 mg capsules: 209161

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