

Duloxetine Sandoz®

duloxetine (as hydrochloride) enteric capsule

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DULOXETINE SANDOZ.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking DULOXETINE SANDOZ against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

What DULOXETINE SANDOZ is used for

DULOXETINE SANDOZ 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.

DULOXETINE SANDOZ is used to treat:

- major depressive disorder (depression)
- generalized Anxiety Disorder (excessive worry)

Ask your doctor if you have any questions about why DULOXETINE SANDOZ has been prescribed for you.

Your doctor may have prescribed DULOXETINE SANDOZ for another reason.

DULOXETINE SANDOZ is available only with a doctor's prescription.

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

Before you take DULOXETINE SANDOZ

When you must not take it

Do not take DULOXETINE SANDOZ if you are allergic to any medicines containing duloxetine hydrochloride or 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 DULOXETINE SANDOZ if you have liver disease.

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

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 DULOXETINE SANDOZ 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 DULOXETINE SANDOZ 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 DULOXETINE SANDOZ with thioridazine, a medicine used to treat schizophrenia.

Do not take DULOXETINE SANDOZ if 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, dyes or preservatives.

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

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.

DULOXETINE SANDOZ 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, DULOXETINE SANDOZ 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 DULOXETINE SANDOZ or the discontinuation of DULOXETINE SANDOZ. 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 DULOXETINE SANDOZ during pregnancy may increase the risk of pre-term birth. If you take

DULOXETINE SANDOZ 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 DULOXETINE SANDOZ so that they can advise you.

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

Breastfeeding while on DULOXETINE SANDOZ is not recommended.

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

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

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

Taking other medicines

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

Some medicines and DULOXETINE SANDOZ 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 DULOXETINE SANDOZ.** You must stop taking DULOXETINE SANDOZ 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 (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 DULOXETINE SANDOZ 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 DULOXETINE SANDOZ.

How to take DULOXETINE SANDOZ

Follow all directions given to you by your doctor and 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 DULOXETINE SANDOZ in Major Depressive Disorder is one 60 mg capsule taken once daily. The recommended dose of DULOXETINE SANDOZ in Generalized 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 DULOXETINE SANDOZ is one 30 mg enteric capsule taken once daily.

How to take DULOXETINE SANDOZ

Swallow the enteric capsule whole with a full glass of water.

Do not open the enteric capsules and crush the pellets inside because the medicine may not work as well. DULOXETINE SANDOZ 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.

If you forget to take DULOXETINE SANDOZ

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

How long to take DULOXETINE SANDOZ for

The length of treatment with DULOXETINE SANDOZ will depend on how quickly your symptoms improve.

Most medicines of this type take time to work so do not 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 take too much DULOXETINE SANDOZ (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 you or anyone else may have taken too much DULOXETINE SANDOZ.

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 heartbeat.

While you are taking DULOXETINE SANDOZ

Things you must do

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

Tell any other doctors, dentists and pharmacists who are treating you that you are taking DULOXETINE SANDOZ.

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 DULOXETINE SANDOZ 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 behavior, irritability or any other unusual changes in behavior 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 use DULOXETINE SANDOZ to treat any other conditions unless your doctor tells you to.

Do not give DULOXETINE SANDOZ to anyone else, even if they have the same condition as you.

Do not stop taking DULOXETINE SANDOZ 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.

DULOXETINE SANDOZ 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 DULOXETINE SANDOZ affects you.

Do not let yourself run out of DULOXETINE SANDOZ 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 *DULOXETINE SANDOZ* can cause severe liver injury.

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

Drinking alcohol with this medicine 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 DULOXETINE SANDOZ.

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

Do not be alarmed by following list 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 *DULOXETINE SANDOZ* 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, sore mouth, thirst, changes to taste
- Burping or belching, indigestion, stomach pain, nausea, vomiting,
- Constipation, diarrhoea, wind (flatulence), loose stools
- Bad breath
- Loss of appetite, weight loss
- Headache
- Trouble sleeping
- Abnormal dreams (including nightmares)
- Drowsiness
- Feeling tired or having no energy, or weakness
- 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, arms, face, mouth, legs and feet
- Yawning
- Throat tightness, difficulty swallowing
- Difficulty starting to urinate (urinary hesitation), incomplete emptying of the bladder (urinary retention) urinating more frequently, pain when urinating, or needing to urinate at night
- Irregular heart beat
- Hot and cold sweats, fever, chills
- Sore ears, sore throat
- Ringing in ears, ear pain

- Muscle pain, cramps, stiffness or twitching
- Changes to the way you walk
- Flushing
- Skin rash
- Restless legs

These are the more common side effects.

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 color. 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 behavior.
- 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 achy, 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 hospitalization.

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 DULOXETINE SANDOZ

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 *DULOXETINE SANDOZ* where children cannot reach it.

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

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

Do not store *DULOXETINE SANDOZ* or any other medicine in the bathroom or near a sink.

Do not leave *DULOXETINE SANDOZ* in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking *DULOXETINE SANDOZ*, or the expiry date has passed, ask your pharmacist what to do with any medicine that are left over.

Product description

What it looks like

DULOXETINE SANDOZ comes in 2 strengths of enteric capsule:

- *DULOXETINE SANDOZ* 30 mg
– Blue/white, opaque capsules, printed with '157' and 'A' in green ink
- *DULOXETINE SANDOZ* 60 mg
– Blue/green, opaque capsules, printed with '158' and 'A' in white ink.

Each blister pack contains 28 enteric capsules.

Ingredients

Active ingredient:

- DULOXETINE SANDOZ 30
mg – 30 mg duloxetine (as
hydrochloride).
- DULOXETINE SANDOZ 60
mg – 60 mg duloxetine (as
hydrochloride).

Inactive ingredients:

- Sugar Spheres
- Hypromellose
- Purified talc
- Sucrose
- Hypromellose phthalate
- Triethyl citrate
- Gelatin
- Titanium dioxide
- Indigo carmine
- Iron oxide yellow (60 mg only)
- Tekprint SB-4020 Green Ink (30
mg only)
- Tekprint SW-0012 White Ink
(60 mg only)

The capsules do not contain gluten
and lactose. The capsules contain
sugars as sucrose, phenylalanine
and sulfites.

Supplier/Distributor

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30 mg enteric capsule: AUST R
199266 (*blisters*)
60 mg enteric capsule: AUST R
199254 (*blisters*)