

DULOXPRA ENTERIC MICROENCAPSULATED CAPSULE

Duloxetine (30mg, 60mg)

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What Duloxpra is used for

Duloxpra is used in adults to treat:

- depression
- generalised anxiety disorder
- diabetic neuropathic pain (often described as burning, stabbing, stinging, shooting or aching or like an electric shock. There may be loss of feeling in the affected area, or sensations such as touch, heat, cold or pressure may cause pain)

How Duloxpra works

Duloxpra contains the active ingredient duloxetine. Duloxpra increases the levels of serotonin and noradrenaline in the nervous system. Duloxpra starts to work in most people with depression or anxiety within two weeks of starting treatment, but it may take 2-4 weeks before you feel better. Tell your doctor if you do not start to feel better after this time. Your doctor may continue to give you Duloxpra when you are feeling better to prevent your depression or anxiety from returning. In people with diabetic neuropathic pain it can take some weeks before you feel better. Talk to your doctor if you do not feel better after 2 months.

Before you use Duloxpra

- When you must not use it

DO NOT take Duloxpra if you:

- are hypersensitive (allergic) to duloxetine or any of the other ingredients of this medicine (see section **Product Description**).
- have liver disease
- have severe kidney disease
- have uncontrolled high blood pressure

Talk to your doctor if you have high blood pressure or heart disease. Your doctor will tell you if you should be taking Duloxpra.

- Before you start to use it

Tell your doctor if any of the following applies to you:

- have kidney disease
- have had seizures (fits)
- have had mania
- suffer from bipolar disorder
- have eye problems, such as certain kinds of glaucoma (increased pressure in the eye)
- have a history of bleeding disorders (tendency to develop bruises)
- are at risk of low sodium levels (for example if you are taking diuretics, especially if you are elderly)
- are currently being treated with another medicine which may cause liver damage

Duloxpra and other antidepressant drugs also may cause symptoms of sexual dysfunction. Ask your doctor and pharmacist before taking this medicine.

Pregnancy and lactation

Talk to your doctor as soon as possible if you are pregnant, if you might be pregnant, or if you are planning to become pregnant.

Tell your doctor if you become pregnant while you are taking Duloxpra. You should use Duloxpra only after discussing the potential benefits and any potential

risks to your unborn child with your doctor.

Make sure your midwife and/or doctor knows you are on Duloxpra. When taken during pregnancy, similar medicines (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you take Duloxpra near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor should be aware that you are taking Duloxpra so they can advise you.

If you take Duloxpra near the end of your pregnancy, your baby might have some symptoms when it is born. These usually begin at birth or within a few days of your baby being born. These symptoms may include floppy muscles, trembling, jitteriness, not feeding properly, trouble with breathing and fits. If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, contact your doctor or midwife who will be able to advise you.

Tell your doctor if you are breastfeeding. The use of Duloxpra while breastfeeding is not recommended. You should ask your doctor or pharmacist for advice.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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Your doctor should decide whether you can take Duloxpra with other medicines.

Do not start or stop taking any medicines before checking with your doctor.

Do not take Duloxpra if you are taking fluvoxamine which is usually used to treat depression and ciprofloxacin or enoxacin which are used to treat some infections.

The main ingredient of Duloxpra, duloxetine, is used in other medicines for other conditions:

- diabetic neuropathic pain, depression and anxiety

Using more than one of these medicines at the same time should be avoided. Check with your doctor if you are already taking other medicines containing duloxetine.

You should also tell your doctor if you are taking any of the following:

Monoamine oxidase inhibitors (MAOIs):

You should not take Duloxpra if you are taking, or have recently taken (within the last 14 days) another antidepressant medicine called a monoamine oxidase inhibitor (MAOI). Examples of MAOIs include moclobemide. Taking a MAOI together with many prescription medicines, including Duloxpra, can cause serious or even life-threatening side effects. You must wait at least 14 days after you have stopped taking an MAOI before you can take Duloxpra. Also, you need to wait at least 5 days after you stop taking Duloxpra before you take a MAOI.

Medicines that cause sleepiness:

These include medicines prescribed by your doctor including benzodiazepines (used to improve sleep or reduce anxiety), medicine similar to morphine, antipsychotics (used to treat mental illness), phenobarbital (used to control fits or improve sleep) and antihistamines (for allergies or colds).

Medicines that increase the level of serotonin:

- Triptans
- Tramadol
- Tryptophan
- Selective serotonin reuptake inhibitors (SSRIs) (such as paroxetine and fluoxetine)
- Serotonin-norepinephrine reuptake inhibitors (SNRIs) (such as venlafaxine)
- Tricyclic antidepressants (such as clomipramine, amitriptyline)
- Pethidine
- St John's Wort
- MAOIs (such as moclobemide and linezolid)

These medicines increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with Duloxpra, you should see your doctor.

Oral anticoagulants or antiplatelet agents: Medicines such as NSAIDs or aspirin which thin the blood or prevent the blood from clotting. These medicines might increase the risk of bleeding.

Duloxpra with food, drink, smoking and alcohol

Duloxpra may be taken with or without food. Care should be taken if you smoke or drink alcohol while you are being treated with Duloxpra.

How to use Duloxpra

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For depression and diabetic neuropathic pain:

The usual dose of Duloxpra is 60 mg to 120 mg once a day, but your doctor will prescribe the dose that is right for you.

For generalised anxiety disorder:

The usual starting dose of Duloxpra is 30 mg once a day after which most individuals will receive 60 mg once a day, but your doctor will prescribe the dose that is right for you. The dose may be adjusted up to 120 mg a day based on your response to Duloxpra.

- When to use it

- Use as directed by your doctor or pharmacist.
- Duloxpra is for oral use. Swallow the capsule whole with a drink of water with or without food.
- To help you remember to take Duloxpra, you may find it easier to take it at the same time every day.

- How long to use it

Continue taking Duloxpra for as long as your doctor recommends.

Talk with your doctor about how long you should keep taking Duloxpra.

DO NOT stop taking Duloxpra, or change your dose, without talking to your doctor. Treating your disorder properly is important to help you get better. If it is not treated, your condition may not go away and may become more serious and difficult to treat.

- If you forget to use it

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual. Do not take a double dose to make up for a forgotten dose. Do not take more than the daily amount of Duloxpra that has been prescribed for you in one day.

- If you use too much (overdose)

Call your doctor or pharmacist immediately if you take more than the amount of Duloxpra prescribed by your doctor. Symptoms of overdose include

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sleepiness, coma, serotonin syndrome (a rare reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles), fits, vomiting and fast heart rate.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking Duloxpra.

- Things you must not do

DO NOT stop taking your capsules without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need Duloxpra he or she will ask you to reduce your dose over at least 1 - 2 weeks before stopping treatment altogether.

Some people who stop taking Duloxpra suddenly have had symptoms such as:

- dizziness, tingling feelings like pins and needles or electric shock-like feelings (particularly in the head), sleep disturbances (intense dreams, inability to sleep), fatigue, sleepiness, feeling agitated, feeling anxious, feeling sick (nausea) or being sick (vomiting), shaking (tremor), headaches, muscle pain, feeling irritable, diarrhoea, excessive sweating or vertigo (spinning sensation).

These symptoms are usually not serious and disappear within a few days, but if you have symptoms that are troublesome you should ask your doctor for advice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things to be careful of

Duloxpra may cause a sensation of restlessness or an inability to sit or stand still. You should tell your doctor if this happens to you.

Medicines like Duloxpra (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about a few weeks but sometimes longer.

You may be more likely to think like this if you:

- have previously had thoughts about killing or harming yourself.
- are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents under 18 years of age

Duloxpra should normally not be used for children and adolescents under 18 years. Also, you should know that individuals under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Duloxpra for individuals under

18 because he/she decides that this is in their best interests.

If your doctor has prescribed Duloxpra for an individual under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when individuals under 18 are taking Duloxpra. Also, the long-term safety effects concerning growth, maturation, and cognitive and behavioural development of Duloxpra in this age group have not yet been demonstrated.

Driving and using machines

Duloxpra may make you feel sleepy or dizzy. Do not drive or use any tools or machines until you know how Duloxpra affects you.

Duloxpra contains sucrose

Duloxpra contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Side effects

Like all medicines, Duloxpra can cause side effects, although not everybody gets them. These effects are normally mild to moderate and often disappear after a few weeks.

Very common side effects:

- headache, feeling sleepy
- feeling sick (nausea), dry mouth

Common side effects:

- lack of appetite
- trouble sleeping, feeling agitated, less sex drive, anxiety, difficulty or failure to experience orgasm, unusual dreams
- dizziness, feeling sluggish, tremor, numbness, including numbness, picking or tingling of the skin
- blurred eyesight
- tinnitus (hearing sound in the ear when there is no external sound)

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- feeling the heart pumping in the chest
- increased blood pressure, flushing
- increased yawning
- constipation, diarrhoea, stomach pain, being sick (vomiting), heartburn or indigestion, breaking wind
- increased sweating, rash
- muscle pain, muscle spasm
- painful urination, frequent urination
- problems getting an erection, changes in ejaculation
- falls (mostly in elderly people), fatigue
- weight loss

Children and adolescents under 18 years of age with depression treated with this medicine had some weight loss when they first start taking this medicine. Weight increased to match other children and adolescents of their age and sex after 6 months of treatment.

Other side effects not listed above may occur in some individuals. Tell your doctor and pharmacist if you notice anything else that is making you feel unwell, even if it is not on this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Duloxpra

- Storage
 - Keep out of the reach and sight of children.
 - Store below 30°C, in the original packing, in order to protect from light and moisture.
- Disposal
 - Do not take Duloxpra after the expiry date which is stated on the pack.
 - If you have any other questions, please talk to your doctor or pharmacist. If your doctor decides to stop treatment, return any left-over capsules to a pharmacist.

- Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

Product Description

- What it looks like

The Duloxpra E.M. Capsule 30mg has a size #3 dark blue cap and white body hard gelatin capsule, cap and body are imprinted with a mark “YSP” on one side and “DUCp” on the other side.

The Duloxpra E.M. Capsule 60mg has a size #1 dark blue cap and light green body hard gelatin capsule, cap and body are imprinted with a mark “YSP” on one side and “DUCp6” on the other side.

- Ingredients

- Active ingredient(s)

The active substance is duloxetine. Each capsule contains 30 or 60 mg of duloxetine (as hydrochloride).

- Inactive ingredients

Capsule content:

sugar spheres, sucrose, hypromellose, talc, carboxymethylethyl cellulose, diacetylated monoglycerides, titanium oxide

- MAL number(s):

DULOXPRA Enteric
Microencapsulated Capsule 30mg
MAL24046043AZ

DULOXPRA Enteric
Microencapsulated Capsule 60mg
MAL24046042AZ

Manufacturer and Product Registration Holder

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