

Driving and using machines

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

Duloxetine capsules contain sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free'.

3. How to take Duloxetine

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

Duloxetine is for oral use. You should swallow your capsule whole with a drink of water.

For depression and diabetic neuropathic pain:

The usual dose of duloxetine is 60 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 duloxetine is 30 mg once a day after which most patients 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 duloxetine.

To help you remember to take Duloxetine, you may find it easier to take it at the same time every day. Talk with your doctor about how long you should keep taking Duloxetine. Do not stop taking Duloxetine, 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 take more Duloxetine than you should

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

If you forget to take Duloxetine

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 Duloxetine that has been prescribed for you in one day.

If you stop taking Duloxetine

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 Duloxetine he or she will ask you to reduce your dose over at least 2 weeks before stopping treatment altogether.

Some patients who stop taking Duloxetine suddenly have had symptoms such as:

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

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.

4. Possible side effects

Like all medicines, this medicine 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 (may affect more than 1 in 10 people)

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

Common side effects (may affect up to 1 in 10 people)

- 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, pricking or tingling of the skin
- blurred eyesight
- tinnitus (hearing sound in the ear when there is no external sound)
- 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, (itchy) 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.

Uncommon side effects (may affect up to 1 in 100 people)

- throat inflammation that causes a hoarse voice
- suicidal thoughts, difficulty sleeping, grinding or clenching the teeth, feeling disorientated, lack of motivation
- sudden involuntary jerks or twitches of the muscles, sensation of restlessness or an inability to sit or stand still, feeling nervous, difficulty concentrating, changes in sense of taste, difficulty controlling movement e.g. lack of coordination or involuntary movements of the muscles, restless legs syndrome, poor sleep quality
- large pupils (the dark centre of the eye), problems with eyesight
- feeling of dizziness or "spinning" (vertigo), ear pain
- fast and/or irregular heart beat
- fainting, dizziness, lightheadedness or fainting on standing up, cold fingers and/or toes

- throat tightness, nose bleeds
- vomiting blood, or black tarry stools (faeces), gastroenteritis, burping, difficulty swallowing
- inflammation of the liver that may cause abdominal pain and yellowing of the skin or whites of the eyes
- night sweats, hives, cold sweats, sensitivity to sunlight, increased tendency to bruise
- muscle tightness, muscle twitching
- difficulty or inability to pass urine, difficulty to start urinating, needing to pass urine during the night, needing to pass more urine than normal, having a decreased urine flow
- abnormal vaginal bleeding, abnormal periods, including heavy, painful, irregular or prolonged periods, unusually light or missed periods, pain in the testicles or scrotum
- chest pain, feeling cold, thirst, shivering, feeling hot, abnormal gait
- weight gain
- Duloxetine may cause effects that you may not be aware of, such as increases in liver enzymes or blood levels of potassium, creatine phosphokinase, sugar, or cholesterol

Rare side effects (may affect up to 1 in 1000 people)

- serious allergic reaction which causes difficulty in breathing or dizziness with swollen tongue or lips, allergic reactions
- decreased thyroid gland activity which can cause tiredness or weight gain
- dehydration, low levels of sodium in the blood (mostly in elderly people; the symptoms may include feeling dizzy, weak, confused, sleepy or very tired, or feeling or being sick, more serious symptoms are fainting, fits or falls), syndrome of inappropriate secretion of anti-diuretic hormone (SIADH)
- suicidal behaviour, mania (over activity, racing thoughts and decreased need for sleep), hallucinations, aggression and anger
- "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
- increased pressure in the eye (glaucoma)
- coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- inflammation of the mouth, passing bright red blood in your stools, bad breath, inflammation of the large intestine (leading to diarrhoea)
- liver failure, yellowing of the skin or whites of the eyes (jaundice)
- Stevens-Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals), serious allergic reaction which causes swelling of the face or throat (angioedema)
- contraction of the jaw muscle
- abnormal urine odour
- menopausal symptoms, abnormal production of breast milk in men or women
- excessive vaginal bleeding shortly after birth (postpartum haemorrhage)

Very rare side effects (may affect up to 1 in 10,000 people)

- inflammation of the blood vessels in the skin (cutaneous vasculitis)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Duloxetine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton.

Do not store above 30°C. Store in the original package to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Duloxetine capsules contain

The **active** substance is duloxetine.

Each 30 mg gastro-resistant capsule, hard contains 30 mg of duloxetine (as hydrochloride).

Each 60 mg gastro-resistant capsule, hard contains 60 mg of duloxetine (as hydrochloride).

The **other** ingredients are:

Capsule content: hypromellose, hypromellose acetate succinate, sucrose, sugar spheres (containing: sucrose, maize starch), glycine talc, titanium dioxide (E171), triethyl citrate.

Capsule shell: gelatin, sodium lauryl sulphate, titanium dioxide (E171), indigo carmine (E132), yellow iron oxide (E172) (60 mg only)

Printing ink: propylene glycol, shellac, yellow iron oxide (E172) (30 mg only), titanium dioxide (E171) (60 mg only), potassium hydroxide (60 mg only).

What Duloxetine capsules look like and contents of the pack

Duloxetine is a gastro-resistant capsule, hard. Each capsule of Duloxetine contains pellets of duloxetine with a covering to protect them from stomach acid.

Duloxetine 30 mg capsules are white to off white spherical pellets filled in size '3' hard gelatin capsules with opaque blue coloured cap and opaque white coloured body, imprinted 'RDY609' on cap and '30mg' on body with golden yellow ink.

Duloxetine 60 mg capsules are white to off white spherical pellets filled in size '1' hard gelatin capsules with opaque blue coloured cap and opaque green coloured body, imprinted 'RDY610' on cap and '60mg' on body with white ink.

Pack sizes of 28, 42, 56, 84 and 98 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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