

Driving and using machines

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

Duloxetine Zentiva 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.

3. How to take Duloxetine Zentiva

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

Call your doctor or pharmacist immediately if you take more than the amount of Duloxetine Zentiva 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 Zentiva

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 Zentiva that has been prescribed for you in one day.

If you stop taking Duloxetine Zentiva

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 Zentiva 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 Zentiva 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, light-headedness 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 Zentiva 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 1,000 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).

Frequency not known

(cannot be estimated from the available data):

- signs and symptoms of a condition called “stress cardiomyopathy” which may include chest pain, shortness of breath, dizziness, fainting, irregular heartbeat.

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 Yellow Card Scheme at: 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 Zentiva

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/blister after EXP. The expiry date refers to the last day of that month.

Store below 30 °C. Store in the original package in order 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 protect the environment.

6. Contents of the pack and other information

What Duloxetine Zentiva contains

The active substance is duloxetine. Each capsule contains duloxetine hydrochloride equivalent to 30 mg or 60 mg duloxetine.

The other ingredients are:

Capsule content: sucrose, maize starch, hypromellose, talc, hypromellose acetate succinate, triethyl citrate.

Capsule shell:

Duloxetine Zentiva 30 mg:

Capsule cap: Indigo carmine (E132), titanium dioxide (E171), gelatin.

Capsule body: titanium dioxide (E171), gelatin.

Duloxetine Zentiva 60 mg:

Capsule cap: Indigo carmine (E132), titanium dioxide (E171), gelatin.

Capsule body: yellow iron oxide (E172), titanium dioxide (E171), gelatin.

What Duloxetine Zentiva looks like and contents of the pack

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

Duloxetine Zentiva is available in 2 strengths: 30 mg and 60 mg.

The 30 mg capsules are hard opaque gelatin capsules of length approx. 15.9 mm with white opaque body and light-blue opaque cap which contain off-white to light-brown-yellow spherical pellets.

The 60 mg capsules are hard opaque gelatin capsules of length approx. 19.4 mm with ivory opaque body and light-blue opaque cap which contain off-white to light-brown-yellow spherical pellets.

Duloxetine Zentiva 30 mg is available in packs of 7, 28, 56, 84 and 98 capsules.

Duloxetine Zentiva 60 mg is available in packs of 14, 28, 56, 84 and 98 capsules.

Not all pack sizes may be marketed.

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