

PATIENT INFORMATION LEAFLET

DULOXX® 30 mg capsule

Oral use.

- **Active ingredient:** Duloxetine

Each capsule contains 33,70 mg of Duloxetine Hydrochloride equivalent to 30 mg of Duloxetine.

- **Excipients:** Sugar pellet, Polysorbate-80, Crospovidone, Hypromellose 6 CPS, Talc, Hypromellose acetate succinate, Triethyl citrate and Titanium dioxide (E171), Gelatine, Capsule composition; FD & C Blue 2 / Indigo carmin (E132)

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet because you may need to read it again.*
- *If you have any further questions or are not sure about anything, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others as it may harm them, even if their symptoms are the same as yours.*
- *Tell your doctor or pharmacist that you use this medicine if you visit your doctor or go to the hospital.*
- *Strictly follow these instructions. Do not take lower or higher doses than the recommended dose.*

What is in this leaflet:

1. ***What DULOXX® is and what it is used for?***
2. ***What you need to know before you use DULOXX®***
3. ***How to use DULOXX®?***
4. ***Possible side effects***
5. ***How to store DULOXX®?***

1. What DULOXX® is and what it is used for?

DULOXX® capsules have an opaque blue cap and opaque white body. DULOXX® is available in packs containing 28 and 56 capsules.

DULOXX® contains gelatin of bovine origin.

Each capsule contains duloxetine pellets coated with a protective layer against gastric acid.

DULOXX® contains the active substance duloxetine. DULOXX® increases the levels of serotonin and noradrenaline in the nervous system.

DULOXX® is used in adults to treat:

- Depression
- 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).
- Generalised anxiety disorder (chronic feeling of anxiety or nervousness)
- Fibromyalgia (fibromyalgia is a musculoskeletal system disorder characterized by pain that can be seen throughout the body, especially in the back, neck and shoulders, accompanied by fatigue).
- Chronic pain (chronic pain felt in bone, joints or muscles, persistent, recurring feeling of distention, pain and/or stiffness)

DULOXX[®] 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 DULOXX[®] 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.

2. What you need to know before you use DULOXX[®]

DULOXX[®] can only be prescribed by a doctor.

The use of antidepressants in children and in young people up to 24 years is likely to increase suicidal thoughts or behavior. Therefore, patients should be monitored closely by their families and caregivers, especially during the onset of treatment and the periods of dose decrease/increase or discontinuation in the first few months, for unexpected behavior changes such as uneasiness, hyperactivity or probability of suicide.

Do not use DULOXX[®]

If you;

- are allergic to duloxetine or any of the other ingredients of DULOXX[®] (see “excipients”)
- have liver disease
- have severe kidney disease
- are taking or have taken within the last 14 days, another medicine known as a monoamine oxidase inhibitor (MAOI) (see ‘Other medicines and DULOXX[®]’)
- are taking fluvoxamine which is usually used to treat depression, ciprofloxacin or enoxacin which are used to treat some infections
- are taking other medicines containing duloxetine (see ‘Other medicines and DULOXX[®]’)
- have uncontrolled narrow-angle glaucoma (Severe pain and visual impairment with sudden increase in intraocular pressure)

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

Take special care with DULOXX[®]

The following are reasons why DULOXX[®] may not be suitable for you. Talk to your doctor before you take DULOXX[®] if you:

- are taking other medicines to treat depression (see ‘Other medicines and DULOXX[®]’)
- are taking St. John’s Wort, a herbal treatment (*Hypericum perforatum*)
- 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
- have hepatitis, increased liver enzymes
- are taking other medicines containing duloxetine (see ‘Other medicines and DULOXX[®]’)
- have akathisia, characterized by a subjectively unpleasant or distressing restlessness and inability to sit or stand still

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

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 two 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

DULOXX® should normally not be used for children and adolescents under 18 years. Also, you should know that patients 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 DULOXX® for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed DULOXX® for a patient 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 patients under 18 are taking DULOXX®. Also, the long-term safety effects concerning growth, maturation, and cognitive and behaviour development of DULOXX® in this age group have not yet been demonstrated.

Please consult your doctor if these warnings apply to you even at any time in the past.

Taking DULOXX® with food and drinks

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

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

You should use DULOXX® only after discussing the potential benefits and any potential risks to your unborn child with your doctor. Do not use DULOXX® during pregnancy unless it is necessary.

Make sure your midwife and/or doctor knows you are on DULOXX®. When taken during pregnancy, similar drugs (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. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you take DULOXX[®] 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 you are concerned about your baby's health, contact your doctor or midwife who will be able to advise you.

If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Breast-feeding:

Ask your doctor or pharmacist for advice before taking this medicine.

Tell your doctor if you are breast-feeding. The use of DULOXX[®] while breastfeeding is not recommended.

Driving and using machines:

DULOXX[®] may make you feel sleepy or dizzy. Do not drive or use any tools or machines until you know how DULOXX[®] affects you.

Important information on some excipients present in DULOXX[®]

DULOXX[®] 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.

Taking other medicines

The main ingredient of DULOXX[®], duloxetine, is used in other medicines for other conditions:

diabetic neuropathic pain, fibromyalgia, chronic pain in bones, joints or muscles, depression, anxiety and urinary incontinence.

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.

Your doctor should decide whether you can take DULOXX[®] with other medicines.

Do not start or stop taking any medicines, including those bought without a prescription and herbal remedies, before checking with your doctor.

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

Monoamine oxidase inhibitors (MAOIs): You should not take DULOXX[®] 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 (an antidepressant) and linezolid (an antibiotic). Taking a MAOI together with many prescription medicines, including DULOXX[®], 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 DULOXX[®]. Also, you need to wait at least 5 days after you stop taking DULOXX[®] before you take a MAOI.

Medicines that cause sleepiness: These include medicines prescribed by your doctor including benzodiazepines, strong painkillers, antipsychotics, phenobarbital and antihistamines.

Medicines that increase the level of serotonin: Triptans, tramadol, tryptophan, SSRIs (such as paroxetine and fluoxetine), SNRIs (such as venlafaxine), tricyclic antidepressants (such as clomipramine, amitriptyline), pethidine, St John's Wort and 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 DULOXX[®], you should see your doctor.

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

CYP1A2 inhibitors like fluvoxamine: DULOXX[®] should not be administered in combination with potent inhibitors of CYP1A2 like fluvoxamine.

Inducers of CYP1A2: Population pharmacokinetic analyses have shown that smokers have almost 50% lower plasma concentrations of duloxetine compared with nonsmokers.

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. HOW TO USE DULOXX[®]

Instructions for proper use and dosage/administration frequency:

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

Route and method of administration:

For the treatment of depression, diabetic neuropathic pain, fibromyalgia and chronic pain:
The usual dose of DULOXX[®] is 30 mg twice a day (2 capsules).

For generalised anxiety disorder:

The usual starting dose of DULOXX[®] 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 DULOXX[®].

If you have the impression that the effect of DULOXX[®] is too strong or weak, talk with your doctor or pharmacist.

Route and method of administration:

DULOXX[®] is for oral use. You should swallow your capsule whole with a drink of water.

To help you remember to take DULOXX[®], 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 DULOXX[®]. Do not stop taking DULOXX[®], 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 have the impression that the effect of DULOXX[®] is too strong or weak, talk with your doctor or pharmacist.

Different age groups:

In children and adolescents:

DULOXX[®] should normally not be used for children and adolescents under 18 years.

In elderly:

There is no specific dose recommendation for patients over 65 years of age.

Special conditions of use:

DULOXX[®] should not be used in patients with end-stage renal disease (requiring dialysis) or with severe renal impairment (estimated creatinine clearance <30 mL / min).

DULOXX[®] should not be used in patients with hepatic impairment.

If you use more DULOXX[®] than you should

Call your doctor or pharmacist immediately if you take more than the amount of DULOXX[®] 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 use more DULOXX[®] than was prescribed, do not worry, tell your doctor or pharmacist.

If you forget to use DULOXX[®]

Do not take double dose to make up the dose you have missed.

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 DULOXX[®] that has been prescribed for you in one day.

Effects that may occur if you stop taking DULOXX[®]

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

Some patients who stop taking DULOXX[®] 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, DULOXX[®] can cause side effects, although not everybody gets them.

Very common	: in at least 1 patient of 10.
Common	: in less than 1 of 10 patients and more than 1 of 100 patients.
Uncommon	: in less than 1 of 100 patients but, more than 1 of 1000 patients.
Rare	: in less than 1 of 1000 patients but more than 1 of 10.000 patients.
Very rare	: in less than 1 of 10.000 patients.
Unknown	: Cannot be estimated based on available data

If any of the following occur, stop using DULOXX[®] and IMMEDIATELY inform your doctor or go to the emergency department of your nearest hospital:

- Serious allergic reactions that cause dizziness or difficulty breathing along with swelling of the lips or tongue
- Stevens-Johnson syndrome (a serious disease with blisters in the skin, mouth, eyes and genital area), angioedema (serious allergic reactions that cause swelling in the face and throat)

Very common

- headache, feeling sleepy
- nausea, dry mouth

Common

- 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, 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
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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

- 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
- DULOXX® 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

- 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)
- inflammation of the mouth, passing bright red blood in your stools, bad breath, inflammation of the large intestine (leading to diarrhea)
- 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

Reporting of suspected adverse reactions

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system. *Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.*

5. How To Store Duloxx®

Store DULOXX® in its original packaging and keep out of the reach and sight of children.
Store at room temperature, below 25°C.

Use in compliance with the expiry date.

Do not use DULOXX® after the expiry date which is stated on the packaging.

Marketing Authorization Holder:

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This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]