Package leaflet: information for the patient

DULONORM 60 mg hard gastro-resistant capsules

Duloxetine, hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. You should not pass it on to others because it may harm them, even if their signs of illness are the same as yours.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What DULONORM is and what it is used for

DULONORM contains the active substance duloxetine. DULONORM increases serotonin and noradrenaline levels in the nervous system.

DULONORM is used in adults to treat:

- depression,
- generalized anxiety disorder (chronic feeling of anxiety or nervousness),
- 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).

DULONORM 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 start feeling better. Tell your doctor if you do not start to feel better after this time. Your doctor may continue to give you DULONORM when you are feeling better to prevent your depression or anxiety from returning.
In people with diabetic neuropathic pain it may take some weeks before you start feeling better.
Talk to your doctor if you do not feel better after 2 months.

2. What you need to know before you take DULONORM

Do not take DULONORM if you:
- are allergic to duloxetine or any of the other ingredients of this medicine (listed in section 6),
- have liver disease,
- have severe kidney disease,
- are taking, or have taken within the last 14 days, another medicine known as monoamine oxidase inhibitor (MAOI) (see "DULONORM and other medicines"),
- 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 "DULONORM and other medicines").

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

Warnings and precautions
The following are reasons why duloxetine may not be suitable for you. Talk to your doctor before you take duloxetine if you:
- are taking other medicines to treat depression (see "DULONORM and other medicines"),
- 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 that may cause liver damage,
- are taking other medicines containing duloxetine (see "DULONORM and other medicines").

Duloxetine 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 thoughts 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 under 25 years of age with psychiatric conditions who are being treated with antidepressants

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
Duloxetine should normally not be used for children or adolescents under 18 years of age. 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 duloxetine for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed duloxetine 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 duloxetine. Also, the long-term safety effects concerning growth, maturation, and cognitive and behavioural development of duloxetine in this age group have not yet been demonstrated.

DULONORM and 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.
The main ingredient of DULONORM, duloxetine, is used in other medicines for other treatments:

- diabetic neuropathic pain, 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 will decide whether you can take duloxetine 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 medicinal products:

Monoamine oxidase inhibitors (MAOIs): you should not take duloxetine 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 duloxetine, can cause serious or even life-threatening side effects. You must wait at least 14 days after you have stopped taking a MAOI before taking duloxetine. Similarly, you need to wait at least 5 days after cessation of duloxetine treatment before starting a MAOI treatment.

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

Medicines that increase serotonin levels: Triptans, tramadol, tryptophan, selective serotonin reuptake inhibitors (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 duloxetine, you should tell your doctor.

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

DULONORM with food, drink and alcohol
DULONORM may be taken with or without food. Care should be taken if you drink alcohol while you are being treated with duloxetine.

Pregnancy and breastfeeding

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

• Tell your doctor if you become pregnant, or you are trying to become pregnant, while you are taking this medicine. You should use duloxetine only after discussing the potential benefits and any potential risk to your unborn child with your doctor.

Make sure your midwife and/or doctor knows that you are taking this medicine. 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 duloxetine near the end of your pregnancy, your baby might have some symptoms when he/she 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 breast-feeding. The use of duloxetine while breastfeeding is not recommended. Ask your doctor or pharmacist for advice.

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.

DULONORM contains sucrose

This medicine contains sucrose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take DULONORM

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

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

For depression and diabetic neuropathic pain:
The recommended dose of DULONORM is 60 mg once a day, but your doctor will prescribe the dose that is right for you.

For generalized anxiety disorder:
The usual starting dose of DULONORM 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 DULONORM.

To help you remember to take DULONORM, you may find it useful to take it at the same times every day.

Talk with your doctor about how long you should keep taking DULONORM. Do not stop taking DULONORM, or change your dose, without talking to your doctor. Treating your disease 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 DULONORM than you should
In the event of an overdose or accidental ingestion, call your doctor or pharmacist immediately or call the Servicio de Información Toxicológica (toxicology information service), tel.: (+34) 91.562.04.20, specifying the medicine and amount taken.
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 forgot to take DULONORM
If you miss a dose, take it as soon as you remember. However, if it is time for the 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 DULONORM that has been prescribed for you in a day.

If you stop taking DULONORM

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

Some patients who stop taking DULONORM 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, nausea or vomiting, 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 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 normally are mild to moderate and often disappear after a few weeks.

Very common side effects (may affect more than 1 in 10 patients)

- headache, somnolence;
- feeling sick (nausea), dry mouth.

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

- loss of appetite;
- trouble sleeping, feeling agitated, less sex drive, anxiety, difficulty or failure to experience orgasm, unusual dreams;
- dizziness, feeling sluggish, tremor, numbness, including drowsiness, pricking or tingling of the skin;
- blurred vision;
- tinnitus (hearing sounds 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 spasms;
- 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 lost when first 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 patients)
• throat inflammation that causes a hoarse voice;
• suicidal thoughts, difficult sleeping, grinding or clenching 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 center of the eye), problems with eyesight;
• feeling of dizziness or 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 1,000 patients)
• 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 intense 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;
• liver failure, yellowing of skin or whites of the eyes (jaundice);

• Stevens-Johnson syndrome (serious illness with blistering of skin, mouth, eyes and genitals), serious allergic reactions which causes face or throat swelling (angioedema);
• jaw muscle contractions;
• abnormal urine odour;
• menopausal symptoms, abnormal production of breast milk in men or women;
• coughing, wheezing and shortness of breath which may be accompanied by a high temperature.

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 (see details below). www.notificaRAM.es. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DULONORM

Keep this medicine out of the sight and reach of children.
Do not store above 30ºC.
Do not use this medicine after the expiry date which is stated on the container after "EXP." The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Dispose of packaging and medicines you no longer need at the recycling containers (SIGRE container in Spain) at your pharmacy. If you are not sure, ask your pharmacist how to throw away medicines and packs you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What DULONORM contains
- The active substance is **duloxetine**.
Each capsule contains 60 mg of duloxetine (as hydrochloride).

- The other ingredients are:
Capsule content: hypromellose, hypromellose acetate succinate, sucrose, sugar spheres (sucrose and maize starch), talc, polyethylene glycol and triethyl citrate. *Capsule shell:* gelatin, titanium dioxide (E171), quinoline yellow (E104), erythrosine red (E127) and indigo carmine (E132).

What the product looks like and contents of the pack
DULONORM is a hard gastro-resistant capsule. Each capsule of DULONORM contains pellets of duloxetine hydrochloride with a covering to protect them from the stomach acid.
DULONORM is available in two strengths: 30 mg and 60 mg.
30 mg capsules are ivory and blue.
DULONORM 60 mg is available in packs of 28 capsules.
Marketing Authorisation Holder and Manufacturer
LABORATORIOS NORMON, S.A.
Ronda de Valdecarrizo, 6 – 28760 Tres Cantos – Madrid (SPAIN)

OTHER PRESENTATIONS
DULONORM 30 mg hard gastro-resistant capsules.

This leaflet was last revised in:

Detailed information on this medicine is available on the web page of the Spanish Agency for Medicines and Healthcare Products website http://www.aemps.gob.es