accord

Package leaflet: Information for the patient

Duloxetine 20mg and 40mg Gastro-resistant Capsules, hard

Duloxetine (as 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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The full name of this medicine is Duloxetine 20mg and 40mg Gastro-resistant Capsules, hard, but within the leaflet it will be referred to as Duloxetine capsules.

What is in this leaflet

1. **What Duloxetine capsules are and what they are used for**
2. **What you need to know before you take Duloxetine capsules**
3. **How to take Duloxetine capsules**
4. **Possible side effects**
5. **How to store Duloxetine capsules**
6. **Contents of the pack and other information**

1. What Duloxetine capsules are and what they are used for

Duloxetine capsules contain the active substance duloxetine. Duloxetine capsules increase the levels of serotonin and noradrenaline in the nervous system.

Duloxetine capsules are a medicine to be taken by mouth to treat Stress Urinary Incontinence (SUI) in women.

Stress urinary incontinence is a medical condition in which patients have accidental loss or leakage of urine during physical exertion or activities such as laughing, coughing, sneezing, lifting or exercise.

Duloxetine capsules are believed to work by increasing the strength of the muscle that holds back urine when you laugh, sneeze or perform physical activities.

The efficacy of Duloxetine capsules is reinforced when combined with a training program called Pelvic Floor Muscle Training (PFMT).

2. What you need to know before you take Duloxetine capsules

Do not take Duloxetine capsules 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 a monoamine oxidase inhibitor (MAOI) (see 'Other medicines and Duloxetine capsules')
- are taking fluvoxamine which is usually used to treat depression, ciprofloxacin or enoxacin which are used to treat some infections.

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

Warnings and precautions

The following are reasons why Duloxetine capsules may not be suitable for you. Talk to your doctor or pharmacist before taking Duloxetine capsules if you:
- suffer from depression or other conditions that are treated with antidepressants. The use of these medicines with duloxetine can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and Duloxetine capsules')
- 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), especially if you are pregnant (see 'Pregnancy and breast-feeding')
- 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
- are taking other medicines containing duloxetine (see 'Other medicines and Duloxetine capsules').

Duloxetine capsules 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 Duloxetine capsules (so called SSRIs/ SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Thoughts of suicide and worsening of depression or anxiety disorder

Although Duloxetine capsules are not indicated for the treatment of depression, its active ingredient (duloxetine) is used as an antidepressant medicine. 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.

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Children and adolescents under 18 years of age

Duloxetine capsules should 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 medicine. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Duloxetine capsules in this age group have not yet been demonstrated.

Other medicines and Duloxetine capsules

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 Duloxetine capsules, duloxetine, is used in other medicines for other conditions: 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 should decide whether you can take Duloxetine capsules 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 Duloxetine capsules if you are taking or have recently taken (within the last 14 days) an 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 capsules, 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 Duloxetine capsules. Also, you need to wait at least 5 days after you stop taking Duloxetine capsules before you take a MAOI.

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

Medicines that increase the level of serotonin: Triptans, tramadol, tryptophan, SSRIs (such as paroxetine, fluoxetine), SNRIs (such as venlafaxine), tricyclic antidepressants (such as clomipramine, amitriptyline), pethidine, St John's Wort and MAOIs (such as moclobemide, linezolid). These medicines increase the risk of side effects; if you get any unusual symptoms whilst taking any of these medicines together with Duloxetine capsules, you should see your doctor.

Buprenorphine/ naloxone (used to treat opioid overdose): These medicines may interact with duloxetine and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

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

Duloxetine capsules with food, drink and alcohol

Duloxetine capsules may be taken with or without food. You should take extra care if you drink alcohol while taking Duloxetine capsules.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, 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 Duloxetine capsules. You should take Duloxetine capsules 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 Duloxetine capsules. 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 capsules 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.
- If you take Duloxetine capsules near the end of your pregnancy there is an increased risk of excessive vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking duloxetine so they can advise you.
- Available data from the use of Duloxetine capsules during the first three months of pregnancy do not show an increased risk of overall birth defects in general in the child. If Duloxetine capsules are taken during the second half of pregnancy, there may be an increased risk that the infant will be born early (6 additional premature infants for every 100 women who take Duloxetine capsules in the second half of pregnancy), mostly between weeks 35 and 36 of pregnancy.
- Tell your doctor if you are breast-feeding. The use of Duloxetine capsules while breast-feeding is not recommended. You should ask your doctor or pharmacist for advice.

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Driving and using machines
Duloxetine capsules may make you feel sleepy or dizzy. Do not drive or use any tools or machines until you know how Duloxetine capsules affect 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 medicinal product.

3. How to take Duloxetine capsules

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 capsules are for oral use. You should swallow your capsule whole with a drink of water.

The recommended dose is 40mg twice a day (in the morning and late afternoon/evening). Your doctor may decide to start your treatment with 20mg twice a day for two weeks before increasing the dose to 40mg twice a day.

To help you remember to take Duloxetine capsules, you may find it easier to take it at the same times every day.

Do not stop taking Duloxetine capsules 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 capsules than you should
Contact your doctor or go to the nearest hospital emergency department immediately if you take more than the amount of Duloxetine capsules 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 capsules
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 number of Duloxetine capsules that has been prescribed for you in one day.

If you stop taking Duloxetine capsules
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 capsules, he or she will ask you to reduce your dose over 2 weeks.

Some patients, who suddenly stop taking Duloxetine capsules after more than 1 week of therapy, 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 short time.

Stop taking Duloxetine capsules and contact your doctor immediately if you experience:
- serious allergic reaction which causes difficulty in breathing or dizziness with swollen tongue or lips
- vomiting blood or black tarry stools (faeces)
- inflammation of the liver that may cause abdominal pain and yellowing of the skin or whites of the eyes
- increased pressure in the eye (glaucoma)
- suicidal behaviour, suicidal thoughts, mania (over activity, racing thoughts and decreased need for sleep), hallucinations, aggression and anger
- 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)
- liver failure, yellowing of the skin or whites of the eyes (jaundice)
- low levels of sodium in the blood (mostly in elderly people; the symptoms may include feeling dizzy, weak, confused, sleepy or very tired, feeling or being sick, more serious symptoms are fainting, fits or falls), syndrome of inappropriate secretion of anti-diuretic hormone (SIADH)
- "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.

Other side effects:
Tell your doctor if you notice any of the following side effects or notice any other effects not listed:
Very common side effects (may affect more than 1 in 10 people)
- feeling sick (nausea), dry mouth, constipation
- fatigue.

Common side effects (may affect up to 1 in 10 people)
- lack of appetite
- trouble sleeping, feeling agitated, less sex drive, anxiety, difficulty sleeping
- headache, dizziness, feeling sluggish, feeling sleepy, tremor, numbness, pricking or tingling of the skin
- blurred eyesight
- feeling of dizziness or "spinning" (vertigo)
- increased blood pressure, flushing
- diarrhoea, stomach pain, being sick (vomiting), heartburn or indigestion
- increased sweating
- weakness, shivering.

Uncommon side effects (may affect up to 1 in 100 people)
- throat inflammation that causes a hoarse voice
- allergic reactions
- decreased thyroid gland activity which can cause tiredness or weight gain
- dehydration
- grinding or clenching the teeth, feeling disorientated, lack of motivation, difficulty or failure to experience orgasm, unusual dreams
- feeling nervous, difficulty concentrating, changes in sense of taste, poor sleep quality
- large pupils (the dark centre of the eye), problems with eyesight, eyes feel dry
- tinnitus (hearing sound in the ear when there is no external sound), ear pain
- feeling the heart pumping in the chest, fast and/or irregular heart beat
- fainting
- increased yawning
- gastroenteritis, inflammation of the mouth, burping, difficulty swallowing, breaking wind, bad breath
- (itchy) rash, night sweats, hives, cold sweats, increased tendency to bruise
- muscle pain, muscle tightness, muscle spasm, contraction of the jaw muscle
- difficulty to start urinating, painful urination, needing to pass urine during the night, frequent urination, abnormal urine odour
- abnormal vaginal bleeding, menopausal symptoms
- chest pain, feeling cold, thirst, feeling hot
- weight loss, weight gain
- Duloxetine capsules 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)
- sudden involuntary jerks or twitches of the muscles, sensation of restlessness or an inability to sit or stand still, difficulty controlling movement e.g. lack of coordination or involuntary movements of the muscles, restless legs syndrome
- dizziness, lightheadedness or fainting on standing up, cold fingers and/or toes
- throat tightness, nose bleeds
- passing bright red blood in your stools, inflammation of the large intestine (leading to diarrhoea)
- sensitivity to sunlight
- muscle twitching
- difficulty or inability to pass urine, needing to pass more urine than normal, having a decreased urine flow
- abnormal periods, including heavy, painful, irregular or prolonged periods, unusually light or missed periods, abnormal production of breast milk
- excessive vaginal bleeding shortly after birth (postpartum haemorrhage)
- falls (mostly in elderly people), abnormal gait
- coughing, wheezing and shortness of breath which may be accompanied by a high temperature.

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, pharmacist or nurse. 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 capsules

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

Do not store above 25°C.

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 capsules contain
The active substance is duloxetine:
Each capsule contains 20mg or 40mg of duloxetine (as hydrochloride).

The other ingredients are:
Capsule content: sugar spheres, hypromellose phthalate, hypromellose, triethyl citrate, hydroxypropyl cellulose, talc.

Capsule shell 20mg: Brilliant Blue FCF(FD&C Blue 1) (E133), titanium dioxide (E171), Hypromellose (E464), edible printing ink.

Capsule shell 40mg: titanium dioxide (E171), yellow iron oxide (E172), Hypromellose (E464), edible printing ink

Edible Printing ink contains: Shellac, propylene glycol, strong ammonia solution, black iron oxide (E172), potassium hydroxide.

What Duloxetine capsules look like and contents of the pack
Duloxetine capsules are hard gastro-resistant capsules. Each Duloxetine capsule contains pellets of duloxetine hydrochloride with a covering to protect them from stomach acid.

Duloxetine capsules are available in 2 strengths: 20mg and 40mg.

The 20mg capsules have an opaque blue body imprinted with 'DLX 20' and an opaque blue cap, imprinted with 'DLX 20'.
The 40mg capsules have an opaque yellow body imprinted with 'DLX 40' and an opaque yellow cap, imprinted with 'DLX 40'.

Duloxetine capsules are available in:
- HDPE containers with PP twist-off cap with integrated silica gel desiccant in pack sizes of 28 and 56 capsules.
- Blister (AL/AL) in pack sizes of 28 and 56 capsules.

Not all pack sizes may be marketed.

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