Package leaflet: information for the patient

[Nationally completed name] 30 mg gastro-resistant hard capsules
[Nationally completed name] 60 mg gastro-resistant hard capsules

duloxetine

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 of the 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 [Nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance duloxetine. [Nationally completed name] increases the levels of serotonin and noradrenaline in the nervous system.

[Nationally completed name] is used in adults to treat:
- depression
- generalised 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)

[Nationally completed name] 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 [Nationally completed name] 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 take [Nationally completed name]

Do not take [Nationally completed name] 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 [Nationally completed name]')
− 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 [Nationally completed name].

Warnings and precautions
- The following are reasons why [Nationally completed name] may not be suitable for you. Talk to your doctor before you take [Nationally completed name] if you:
- are taking other medicines to treat depression (see 'Other medicines and [Nationally completed name]')
- 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 [Nationally completed name]')

[Nationally completed name] 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 [Nationally completed name] (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 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

[Nationally completed name] 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, a doctor may prescribe [Nationally completed name] for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed [Nationally completed name] 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 [Nationally completed name]. Also, the long-term safety effects concerning growth, maturation, and cognitive and behavioural development of [Nationally completed name] in this age group have not yet been demonstrated.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The main ingredient of [Nationally completed name], 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 [Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name], 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 [Nationally completed name]. Also, you need to wait at least 5 days after you stop taking [Nationally completed name] 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 [Nationally completed name], 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.

[Nationally completed name] with food, drink and alcohol
[Nationally completed name] may be taken with or without food. Care should be taken if you drink alcohol while you are being treated with [Nationally completed name].

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 [Nationally completed name]. You should use [Nationally completed name] 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 [Nationally completed name]. When taken during pregnancy, similar medicines (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 [Nationally completed name] 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 [Nationally completed name] 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 during the first three months of pregnancy do not show an increased risk of overall birth defects in general in the child. If [Nationally completed name] is 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 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 [Nationally completed name] while breast-feeding is not recommended. You should ask your doctor or pharmacist for advice.

Driving and using machines
[Nationally completed name] may make you feel sleepy or dizzy. Do not drive or use any tools or machines until you know how [Nationally completed name] affects you.

[Nationally completed name] contains lactose, Allura Red AC (E 129), sodium and Sunset Yellow FCF (E 110)
This medicine contains lactose. 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 Allura Red AC (E 129), which may cause allergic reactions.
This medicine contains less than 1 mmol sodium (23 mg) per gastro-resistant hard capsule, that is to say essentially 'sodium-free'.
60 mg gastro-resistant hard capsule additionally
This medicine contains Sunset Yellow FCF (E 110), which may cause allergic reactions.

3. How to take [Nationally completed name]

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

For depression and diabetic neuropathic pain:

The usual dose of [Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name].

[Nationally completed name] is for oral use. You should swallow your capsule whole with a drink of water.

To help you remember to take [Nationally completed name], 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 [Nationally completed name]. Do not stop taking [Nationally completed name], 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 [Nationally completed name] than you should
Call your doctor or pharmacist immediately if you take more than the amount of [Nationally completed name] 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 [Nationally completed name]
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 [Nationally completed name] that has been prescribed for you in one day.

If you stop taking [Nationally completed name]
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 [Nationally completed name]he or she will ask you to reduce your dose over at least 2 weeks before stopping treatment altogether.

Some patients who stop taking [Nationally completed name] 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

[Nationally completed name] 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)
- Coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- 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 behavior
- 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 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store **[Nationally completed name]**

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

Do not store above 30°C.
HDPE bottles:
After first opening, use within 30 days.

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 [Nationally completed name] contains

- The active substance is duloxetine.
  Each gastro-resistant hard capsule contains 30 mg of duloxetine (as hydrochloride).
  Each gastro-resistant hard capsule contains 60 mg of duloxetine (as hydrochloride).
- The other ingredients are:

Capsule content: pregelatinised starch (maize), microcrystaline cellulose, povidone K30, talc, magnesium stearate, sodium stearyl fumarate, hypromellose acetate succinate, titanium dioxide (E 171), lactose monohydrate, hypromellose and macrogol 4000.

Capsule shell: titanium dioxide (E 171), gelatin, Brilliant Blue FCF (E 133), Allura Red AC (E 129).
60 mg gastro-resistant hard capsule additionally
Quinoline yellow (E 104) and Sunset Yellow FCF (E 110)

Printing ink: shellac glaze, indigo carmine aluminum lake (E 132)**,** titanium dioxide (E 171)**,** propylene glycol (E 1520).

What [Nationally completed name] looks like and contents of the pack

30 mg gastro-resistant hard capsules
Opaque dark blue cap and opaque white body capsule, size 2, imprinted with “30”, containing 4 white to off white, round, biconvex tablets.

60 mg gastro-resistant hard capsules
Opaque dark blue cap and opaque yellowish green body capsule, size 0E, imprinted with “60”, containing 8 white to off white, round, biconvex tablets.

The gastro-resistant hard capsules are packed in PVC/PE/PCTFE/aluminium blisters or in PA/aluminium/PVC/aluminium blisters or are packed in a HDPE bottle with child resistant PP screw cap and inserted in a carton.

Pack sizes:
Blister: 7, 14, 28, 30, 50, 56, 84, 98 gastro-resistant hard capsules
Bottle: 30 gastro-resistant hard capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed nationally]

This leaflet was last revised in {MM/YYYY}.
[To be completed nationally]