1. What Duloxetine is and what it is used for

This medicine contains the active substance Duloxetine. Duloxetine is used for various conditions of the central and peripheral nervous system.

Duloxetine is used in adults to treat:

- generalized anxiety disorder (feeling of anxiety or worry that is not based on any real problem)
- depression
- diabetic neuropathic pain (often described as burning, stabbing, touch, heat, cold or pressure may cause pain)

• have any blood disorders (may cause loss of blood or make the blood flow more easily)
• have had mania

Duloxetine is not recommended for children and adolescents under 18 years of age.

2. What you need to know before you take Duloxetine

If you get any side effects, talk to your doctor or pharmacist. This includes any possible adverse effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Duloxetine is and what it is used for
2. What you need to know before you take Duloxetine
3. How to take Duloxetine
4. Possible side effects
5. How to stop taking Duloxetine
6. Contents of this pack and other information

Duloxetine contains Duloxetine 60 mg gastro-resistant capsules (Enteric coated)

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

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The following are reasons why Duloxetine may not be suitable for you:

• have a history of bleeding disorders (tendency to develop bruises or cuts)
• have a history of seizures (fits)
• are taking or have taken within the last 14 days a monoamine oxidase inhibitor (MAOI; see section 4.4. Other medicines and Duloxetine)
• have liver disease

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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.

3. How to take Duloxetine

Duloxetine may make you feel sleepy or dizzy.

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Duloxetine may be prescribed before starting another antidepressant, such as citalopram, paroxetine, amitriptyline, clomipramine, amitriptyline, desipramine, or tricyclic antidepressants, or for patients with persistent pulmonary hypertension of the newborn (PPHN), multiple chemical sensitivity, or other allergies. Contact your doctor if you have any of these conditions.

If you feel your baby is not feeding properly, contact your doctor or midwife who will be able to advise you.

Source: Duloxetine 60 mg gastro-resistant capsules Package leaflet: Information for the patient

Please take this leaflet with you when you take your medicine (or are planning to have a baby, ask your doctor or pharmacist for advice). Should you want to discuss this, please go back to your doctor. You should only stop taking Duloxetine if your doctor tells you to do so. You should not stop taking Duloxetine within at least 14 days after you have stopped taking a MAOI before you start taking Duloxetine because this may increase the risk of serious side effects.

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Monoamine oxidase inhibitors (MAOIs): You should not take Duloxetine with food, drink and alcohol

• Tell your doctor if you are breast-feeding. The use of Duloxetine while breastfeeding is not recommended. You should ask your doctor or pharmacist for advice.

Driving and using machines:

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Duloxetine and breastfeeding

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### 4. Possible side effects

#### Generalised anxiety disorder
- Increased anxiety
- Increased heart rate
- Dizziness
- Headache
- Fatigue
- Sleep disturbances (vivid dreams, nightmares, inability to fall asleep or stay asleep)
- Lumbar pain
- Leg cramps
- Automatic nervous system disorders (abnormal sweating, palpitations)
- Nervousness
- Unsteadiness

#### Depression and diabetic neuropathic pain
- Restlessness, feeling of being drunk, fever, sweating or rigid muscles
- Feelings of great happiness, drowsiness, clumsiness
- Disturbance in the development of the nervous system
- Palpitations
- Chest tightness
- Abnormal electrocardiogram

#### Other side effects
- Sleepiness, feeling restless or agitated
- Lack of appetite
- Loss of appetite
- Loss of weight
- Muscle cramps
- Muscle weakness
- Sweating
- Discomfort
- Cold hands and/or feet
- Stomach pain
- Upset stomach
- Diarrhoea
- Headache
- Rash
- Skin irritation
- Swelling
- Blistering of the skin, mouth, eyes and genitals
- Pneumonitis

#### Rare side effects
- Suicidal behaviour, mania (over activity, racing thoughts, erratic mood)
- Seizures
- Slow heartbeat
- Abnormal electrocardiogram
- Electrolyte imbalances (sodium and potassium)
- Coughing, wheezing and shortness of breath
- Stevens-Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals)
- Fever, shingles, fever, rash
- Tissue injury
- Inability to stop or control bleeding
- Inability to use or feel limbs

### 5. How to store Duloxetine

- Keep the medicine out of the reach of children and pets.
- Store in the original package in order to protect from light.
- Do not store in the refrigerator. Do not use if the capsule blister is damaged.
- Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of the month.

### 6. Contents of the pack and other information

**Duloxetine contains sucrose.**

**Duloxetine hydrochloride capsules, ink (shellac, black iron oxide (E172), propylene glycol, gelatin, PVA, water).**

**Capsule contents:** sugar spheres (sucrose, maize starch), hypoallergenic pharmaceutical talc, magnesium stearate, colloidal silicon dioxide, titanium dioxide (E171), lactose (as duloxetine hydrochloride).