MACXETINE 30MG/60MG CAPSULE

Duloxetine Delayed Release Capsule 30/60mg

What is in this leaflet?

1. What Macxetine is used for:

Duloxetine is used 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.

2. How Macxetine works:

Macxetine contains the active ingredient duloxetine. Duloxetine increases the levels of serotonin and noradrenaline in the nervous system. Duloxetine 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 Duloxetine 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

3. Before You Use Macxetine:

When you must not use it

- If you are allergic to duloxetine or any of the other ingredients of this medicine.
- If you have liver disease
- If you have severe kidney disease
- If you are taking fluvoxamine which is usually used to treat depression.

- Before you start to use it

Talk to your doctor or pharmacist before taking Macxetine**.** Take special care:

- If you are taking other medicines to treat depression
- If you are taking St. John's Wort, a herbal treatment (Hypericum perforatum)
- If you have kidney disease
- If you have had seizures (fits)
- If you have had mania
- If you suffer from bipolar disorder
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye)
- If you have a history of bleeding disorders (tendency to develop bruises)
- If you are at risk of low sodium levels (for example if you are taking diuretics, especially if you are elderly)
- If you are currently being treated with another medicine which may cause liver damage

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 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.

Children and adolescents under 18 years of age

Duloxetine 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 attempts, suicidal thoughts and hostility (predominately 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 interest.

- Taking other medicines:

Tell your doctor or pharmacist about any other medicines that you are taking, took recently or might take. 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 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 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. 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 an MAOI before you can take duloxetine. Also, you need to wait at least 5 days after you stop taking duloxetine before you take a MAOI.
- *Medicines that cause sleepiness*: These include medicines prescribed by your doctor including benzodiazepines (used to improve sleep or reduce anxiety), medicine similar to morphine, antipsychotics (used to treat mental illness), phenobarbital (used to control fits or improve sleep) and antihistamines (for allergies or colds).
- *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 Duloxetine, you should see your doctor.
- *Oral anticoagulants or antiplatelet agents***:** Medicines such as NSAIDs or aspirin which thin the blood or prevent the blood from clotting. These medicines might increase the risk of bleeding.

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4. How to use Macxetine:

- How much to use

For depression and diabetic neuropathic pain: The usual dose of Duloxetine is 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 Duloxetine

For generalised anxiety disorder: The usual starting dose of Duloxetine 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 Duloxetine.

-When to use

Use as directed by your doctor or pharmacist

*-How long to use it***.**

You should continue to take Duloxetine for as long as instructed by your doctor

-If you forget to use Macxetine

If you accidentally miss a dose then simply use your normal dose when the next one is due. Do not use a double dose to make up for a missed or forgotten dose.

-If you use Macxetine too much (Overdose)

If you take more than the prescribed dose of Duloxetine, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort. 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.

Take the Duloxetine box/container with you when you go to the doctor or hospital.

5. While you are using Macxetine :

- Things you must do

Duloxetine *can be taken with or without food.* Care should be taken if you drink alcohol while you are being treated with Duloxetine.

- Things you must not do

Driving and using machines

You are advised not to drive a car or operate machinery until you know how Duloxetine affects you.

- Things to be careful of:

Pregnancy and breast-feeding

Inform your doctor if you are pregnant or planning to become pregnant. Do not take Duloxetine if you are pregnant or breast-feeding, unless you and your doctor have discussed the risks and benefits involved.

Make sure your doctor know you are on Duloxetine. 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 doctor immediately.

If you take Duloxetine 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 who will be able to advise you.

Use in breast-feeding

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.

Duloxetine 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.

6. 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

- headache, feeling sleepy
- feeling sick (nausea), dry mouth

Common side effects

- 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, 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.

Reporting of side effects

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal Of Macxetine:

Storage

Store below 30°C in a dry place, protected from light. Keep out of the reach and sight of children.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away the medicines you no longer use. These measures will help to protect the

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environment

8. Product Description

What it looks like

30 mg: Opaque blue cap/opaque white body "3" capsules containing white to off white coloured pellets with C83 on cap imprinted with white ink.

60 mg: Opaque blue cap/ opaque green body, size "1" capsules containing, white to off white coloured pellets with "C81" on cap imprinted with white ink..

Ingredients

*Active ingredient**:***
Duloxetine Hydrochloride

*Inactive Ingredients***:**
Sugar Spheres ; Hypromellose 2910 (Methocel E5 Premium LV) ; Sucrose; Sodium Lauryl Sulphate ; Purified water; Polyethylene Glycol / Macrogol ; Hypromellose Phthalate (HP 50) ; Hypromellose Phthalate (HP 55) ; Triethyl Citrate & Talc .

MAL NUMBER:
Macxetine 30mg: MAL19046011AZ
Macxetine 60mg: MAL19046010AZ

9. Manufacturer

Macleods Pharmaceuticals Ltd. Block N2, Village Theda, Post office Lodhimajra, Tehsil Baddi, District Solan, Himachal Pradesh, IN-174101, India Office: Atlanta Arcade, Marol Church Road, Andheri-Kurla Road, Andheri (East) Mumbai - 400059. INDIA.

Product Registration Holder in Malaysia

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10. Date of Revision

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