

DULOX 30/60 (Duloxetine Hydrochloride Delayed Release Capsules 30mg / 60mg)

Duloxetine hydrochloride (30mg/60 mg)

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What *DULOX 30 & 60* is used for

Duloxetine is used to treat major depressive disorder and general anxiety disorder.

Duloxetine is also used to treat pain caused by nerve damage in people with diabetes (diabetic neuropathy).

How *DULOX 30 & 60* works

Duloxetine affects chemicals in the brain that may become unbalanced and cause depression.

Before you use *DULOX 30 & 60*

- When you must not use it

Pregnancy and lactation

Do not take *DULOX 30 & 60* if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *DULOX 30 & 60* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Do not use this medication if you are allergic to duloxetine, or if you have untreated or uncontrolled high blood pressure.

Do not use duloxetine if you have taken an MAO inhibitor in the past 14 days. A dangerous drug interaction could occur. MAO inhibitors include furazolidone, isocarboxazid, linezolid, phenelzine, rasagiline, selegiline, and tranylcypromine. After you stop taking

duloxetine, you must wait at least 5 days before you start taking an MAOI.

To make sure duloxetine is safe for you, tell your doctor if you have:

- liver or kidney disease;
- seizures or epilepsy;
- a bleeding or blood clotting disorder;
- high blood pressure;
- glaucoma;
- bipolar disorder (manic depression);
- a history of drug abuse or suicidal thoughts

Some young people have thoughts about suicide when first taking an antidepressant. Your doctor will need to check your progress at regular visits while you are using duloxetine. Your family or other caregivers should also be alert to changes in your mood or symptoms.

It is not known whether duloxetine will harm an unborn baby. However, duloxetine may cause problems in a newborn if you take the medicine during the third trimester of pregnancy. Tell your doctor if you are pregnant or plan to become pregnant while using this medication.

Duloxetine can pass into breast milk and may harm a nursing baby. You should not breast-feed while taking this medication.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Many drugs can interact with duloxetine. Not all possible interactions are listed here. Tell your doctor about all your medications and any you start or stop using during treatment with duloxetine, especially:

- a blood thinner such as warfarin
- monoamine oxidase inhibitors (MAOIs) such as moclobemide and linezolid
- CYP1A2 inhibitor such as fluvoxamine
- alcohol
- St. John's wort
- Tramadol
- Pethidine
- tryptophan
- tricyclic antidepressants such as amitriptyline, nortriptyline
- risperidone

How to use *DULOX 30 & 60*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The general dose is 60mg once daily.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *DULOX 30 & 60* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much

of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking **DULOX 30 & 60**

Tell your doctor immediately if you become pregnant while taking this medication.

- Try to take the medicine at the same time each day. Follow the directions on your prescription label.
- Do not crush, chew, break, or open an extended-release capsule. Swallow it whole.
- It may take 4 weeks or longer before your symptoms improve. Keep using the medication as directed. Do not stop using duloxetine without first talking to your doctor. You may have unpleasant side effects if you stop taking this medication suddenly.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give **DULOX 30 & 60** to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, **DULOX 30 & 60** can cause side effects, although not everybody gets them.

DULOX 30 & 60 have the following common side effects:

- Nausea
- Headache
- Dry mouth
- Dizziness
- Drowsiness

Get emergency medical help if you have any of these **signs of an allergic reaction**: skin rash; difficulty breathing; swelling of your face, lips, tongue, or throat.

Report any new or worsening symptoms to your doctor, such as: mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Other side effects include infection of the throat or throat tightness, low thyroid levels, decreased appetite, high blood sugar levels, dehydration, low sodium levels, tremor, nerve or muscle disturbances, involuntary movement, visual or hearing disturbances, palpitations, faster heartbeats, high blood pressure, stomach disorders, liver or kidney impairment, skin disorders, general unwellness, disorders with the private parts, decrease weight and increased some blood levels.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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)]

Storage and Disposal of **DULOX 30 & 60**

- Storage

Keep out of the reach and sight of children.

Store below 30 °C and protect from moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

- **DULOX 30 & 60**

DULOX 30

Opaque blue cap / Opaque white body size '3' hard gelatin capsules imprinted with 'H' on cap and '191' on body with golden yellow ink, filled with white to off white colored pellets.

DULOX 60

Opaque blue cap / Opaque green body size '1' hard gelatin capsules imprinted with 'H' on cap and '192' on body with white ink, filled with white to off white colored pellets.

- Ingredients

- Active ingredient(s)
Duloxetine hydrochloride

- Inactive ingredients

Sugar spheres, Hypromellose 2910
Crospovidone (Kollidon CL-M),
Talc, Sucrose, Purified water,
Carboxymethyl cellulose,
Povidone, Isopropyl alcohol,
Opadry white YS-1-7003

MAL number:

DULOX 30

MAL18116134AZ

DULOX 60

MAL18116135AZ

Nombor Siri

NPRA(R2/1)250314/1436

Manufacturer

HETERO LABS LIMITED

Unit-III, 22-110, I.D.A.,

Jeedimetla, Hyderabad,

Telangana state, INDIA.

Product Registration Holder

CAMBER LABORATORIES SDN BHD

Unit E-13A-02, Menara SUEZCAP 2, No. 2, KL Gateway,

Jalan Kerinchi, Gerbang Kerinchi Lestari,

59200 Kuala Lumpur, Malaysia.

Date of revision

Mar 2025