

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S5**

CYMBALTA 30 (hard gastro-resistant capsules)

CYMBALTA 60 (hard gastro-resistant capsules)

Duloxetine (as hydrochloride)

Contains sugar: 56/111 mg sucrose

Read all of this leaflet carefully before you start taking **CYMBALTA**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **CYMBALTA** has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

What is in this leaflet

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

1. What **CYMBALTA** is and what it is used for

The active substance is duloxetine hydrochloride.

CYMBALTA is a serotonin and norepinephrine reuptake inhibitor and increases the levels of serotonin and noradrenaline in the nervous system.

CYMBALTA is used in adults to treat

- depression
- diabetic peripheral neuropathic pain.

CYMBALTA may take 2 to 4 weeks to start working in most people with depression. Talk to your doctor if you do not start to feel better after this time.

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 CYMBALTA

Do not take CYMBALTA:

- If you are hypersensitive (allergic) to duloxetine or any of the other ingredients of CYMBALTA (listed in section 6).
- If you are taking or have recently taken within the last 14 days, another antidepressant medicine known as monoamine oxidase inhibitor (MAOI) or linezolid. Taking CYMBALTA with a MAOI or linezolid could cause serious side effects or be life-threatening.
- If you have liver disease.
- If you have severe kidney disease.
- If you are pregnant or breastfeeding your baby.
- If you are under 18 years of age.

Warnings and precautions

Take special care with CYMBALTA:

- If you have thoughts of suicide and worsening of your depression:

If you are depressed, 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.
- If you 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 antidepressants.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behavior.

- If you have had previous episodes of mania.
- If you have had previous episodes of seizures/fits.
- 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 or had kidney problems. You may need a lower dose.
- If you have or had liver problems. You may need a lower dose.
- If you have high blood pressure.
- If you are currently being treated with another medicine which may cause liver damage.
- If you have a history of bleeding disorders (tendency to develop bruises), especially if you are pregnant (see 'Pregnancy and breast-feeding').
- If you are at risk of having low sodium levels (for example if you are taking diuretics, especially if you are elderly).
- If you are taking St. John's Wort (*Hypericum perforatum*), a herbal treatment.

- CYMBALTA may cause a sensation of restlessness or an inability to sit or stand still. You should tell your doctor if this happens to you.
- If you are taking other medicines containing duloxetine (see 'Other medicines and CYMBALTA').
- CYMBALTA may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Other medicines and CYMBALTA

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Your doctor should decide whether you can take CYMBALTA 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 tell your doctor if you are taking any of the following:

Monoamine Oxidase Inhibitors (MAOIs): You should not take CYMBALTA if you are taking, or have recently taken within the last 14 days, another antidepressant medicine called a monoamine oxidase inhibitor (MAOI). Taking a MAOI together with many prescription medicines, including CYMBALTA can cause serious or even life-threatening side effects. You must wait at least 14 days after you have stopped taking MAOI before you can take CYMBALTA. Also you need to wait at least 5 days after taking CYMBALTA before you can take MAOI.

Medicines that increase levels of serotonin:

Tell your doctor if you are taking any medicines that act in the same manner as CYMBALTA.

Examples of these medicines include triptans, tramadol, tryptophan, SSRI (such as paroxetine and fluoxetine) and SNRI's (such as venlafaxine), tricyclic antidepressants (such as clomipramine,

amitriptyline), pethidine and St. John's Wort. These medicines increase the risk of side effects. Tell your doctor if you get any symptoms.

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

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

Taking CYMBALTA with food and drink

CYMBALTA may be taken with or without food. Care should be taken if you drink alcohol while you are being treated with CYMBALTA.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take CYMBALTA if you are pregnant.

Taking CYMBALTA while you are pregnant may result in:

- your baby being born with some symptoms. 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.
- 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.

- an increased risk that the infant will be born early.
- an increased 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 are taking CYMBALTA you should not breastfeed your baby.

Driving and using machinery

Do not drive or operate any tools or machines because CYMBALTA can make you sleep.

It is not always possible to predict to what extent CYMBALTA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CYMBALTA affects them.

CYMBALTA contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CYMBALTA.

CYMBALTA contains sodium

CYMBALTA contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take CYMBALTA

- Do not share medicines prescribed for you with any other person.

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

For depression and diabetic peripheral neuropathic pain:

- The usual dose of CYMBALTA is 60 mg capsule once a day, but your doctor will prescribe the dose that is right for you.
- You can take CYMBALTA with or without food. You should swallow the capsule whole with water.
- Your doctor will tell you how long your treatment with CYMBALTA will last. If you have the impression that the effect of CYMBALTA is too strong or too weak, talk to your doctor or pharmacist.

If you take more CYMBALTA than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose include sleepiness, coma, serotonin syndrome (a 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 CYMBALTA

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 more than your total daily dose in any 24-hour period.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking CYMBALTA

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 CYMBALTA, he will ask you to reduce your dose over at least 2 weeks before stopping treatment altogether.

Some patients who stop taking CYMBALTA suddenly have had symptoms such as dizziness, fatigue, tingling feelings like pins and needles, sleep disturbances (nightmares, inability to sleep, vivid dreams) feeling restless or agitated, feeling anxious, feeling sick (nausea) or being sick (vomiting), tremor (shakiness), headaches, 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.

4. Possible side effects

CYMBALTA can have side effects.

Not all side effects reported for CYMBALTA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CYMBALTA, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking CYMBALTA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CYMBALTA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Feeling sleepy
- Dry mouth
- Feeling sick (nausea)
- Lack of appetite
- Trouble sleeping, anxiety, feeling agitated, less sex drive, difficulty or failure to experience orgasm, unusual dreams
- Dizziness, feeling sluggish, tremor, numbness, prickling 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, being sick (vomiting), heartburn or indigestion, stomach pain, breaking wind
- Increased sweating, feeling itchy
- Muscle pain, muscle spasm
- Frequent urination, painful urination
- Problems getting an erection, changes in ejaculation
- Falls (mostly in elderly people), feeling tired
- Weight loss

Less frequent side effects:

- Throat inflammation that causes a hoarse voice

- Suicidal thoughts
- Difficulty sleeping, grinding or clenching the teeth, feeling disorientated, lack of motivation
- Difficulty concentrating, changes in sense of taste, sudden involuntary jerks or twitches of the muscles, poor sleep quality, restless leg syndrome
- Large pupils (dark centre of the eye), problems with eyesight, dry eye
- Feeling of dizziness or “spinning” (vertigo), ear pain
- Fast and/or irregular heartbeat
- Fainting, dizziness, light-headedness or fainting on standing up, cold fingers and/or toes, nose bleeds
- Burping, inflammation of the stomach and/or intestines, bleeding of the stomach and/or intestines, difficulty swallowing
- Night sweats, sensitivity to sunlight, cold sweat, inflammation of the skin when in contact with a substance, contact dermatitis, 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
- Changes in ejaculation, abnormal sexual function,
- Feeling abnormal, feeling cold, feeling hot, thirst, chills, abnormal gait
- Increased liver enzymes, increased weight
- Decreased thyroid gland activity which can cause tiredness or weight gain
- Dehydration
- Irregular involuntary contraction of muscles
- Throat tightness
- Inflammation of the mucous membranes of the mouth, bad breath
- Abnormal urine odour

- Pain in the testicles, abnormal vaginal bleeding, abnormal periods, including heavy, painful, irregular or prolonged periods, unusually light or missed periods, menopausal symptoms
- Increased blood cholesterol
- Sudden onset of chest pain, difficulty breathing, palpitations, nausea and/or vomiting, in response to stress.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. Alternatively, report suspected adverse events to the company at ade_za@lilly.com. By reporting side effects, you can help provide more information on the safety of CYMBALTA.

5. How to store CYMBALTA

Store all medicines out of reach of children.

Store at or below 30 °C in original blister packs.

Do not use after expiry date stated on the carton.

Store in the original carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CYMBALTA contains

The active substance is duloxetine.

Each CYMBALTA 30 capsule contains 30 mg duloxetine (as hydrochloride).

Each CYMBALTA 60 capsule contains 60 mg duloxetine (as hydrochloride).

The other ingredients are:

Capsule content: hypromellose, hypromellose acetate succinate, sucrose, sugar spheres, talc, titanium dioxide, triethyl citrate.

Capsule shell: gelatin, sodium lauryl sulfate, titanium dioxide, indigo carmine, edible green ink for the 30 mg, yellow iron oxide and edible white ink for the 60 mg.

What CYMBALTA looks like and contents of the pack

CYMBALTA 30 (Capsule), has an opaque white body and opaque blue cap and is imprinted with "30 mg" on the body in green ink. The capsule contains white to light greyish white enteric coated pellets.

CYMBALTA 60 (Capsule), has an opaque green body and opaque blue cap and is imprinted with "60 mg" on the body in white ink. The capsule contains white to light greyish white enteric coated pellets.

CYMBALTA capsules are supplied in blister packs composed of cold-form aluminium laminate on one side and vinyl coated aluminium foil on the other side and packed in cartons of 28 capsules.

Holder of Certificate of Registration

Eli Lilly (S.A.) (Pty) Ltd.

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Registration numbers

CYMBALTA 30: 37/1.2/0299

CYMBALTA 60: 37/1.2/0301

Registration Details for Botswana: Schedule 2	
Cymbalta 30 mg Capsules	Reg. No.: BOT0700951
Cymbalta 60 mg Capsules	Reg. No.: BOT0700950
Registration Details for Namibia: Schedule NS3	
Cymbalta 30 mg Capsules	Reg. No.: 06/1.2/0006
Cymbalta 60 mg Capsules	Reg. No.: 06/1.2/0007