

**Patient Package Leaflet in Accordance
with the Pharmacists' Regulations (Preparations) - 1986**
This medicine is dispensed with a physician's prescription only

Cymbalta 30 mg

Gastro-resistant capsules

Active ingredient:

duloxetine (as hydrochloride) 30 mg

Cymbalta 60 mg

Gastro-resistant capsules

Active ingredient:

duloxetine (as hydrochloride) 60 mg

Inactive ingredients and allergens in the preparation: See Chapter 2 section "Important information about some of the ingredients of this medicine" and Chapter 6 "Additional information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, contact your doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.

Antidepressants and anti-anxiety medicines increase the risk of suicidal behavior and thoughts among children, adolescents and young adults up to 24 years of age. When beginning treatment with this medicine, patients of all ages and their relatives, must monitor behavioral changes such as worsening of depression, suicidal thoughts, aggressiveness etc. If changes such as these occur, contact the doctor immediately.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Cymbalta is used to treat adults suffering from:

- major depressive episodes
- neuropathic pain associated with peripheral diabetic neuropathy
- generalized anxiety disorder (GAD)
- fibromyalgia
- chronic musculoskeletal pain when other therapies have failed or are contra-indicated. This has been established in studies in patients with chronic low back pain (CLBP) and chronic pain due to osteoarthritis.

Therapeutic group: **Cymbalta** belongs to the SNRI family of drugs and causes an increase in the serotonin and noradrenaline levels.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (see Chapter 6 "Additional information").

- you suffer from a liver disease.
- you suffer from a severe kidney disease.
- you are taking or have taken within the last 14 days another medicine known as a monoamine oxidase inhibitor (MAOI), including intravenous methylene blue and the antibiotic linezolid. Do not start treatment with a monoamine oxidase inhibitor-type drug unless at least 5 days have passed since the cessation of treatment with **Cymbalta**; see “Drug interactions”.
- you are taking thioridazine.

Special warnings regarding the use of this medicine:

Before starting treatment with Cymbalta, tell your doctor if you:

- suffer from a kidney disease
- suffer or have suffered in the past from seizures (convulsions)
- suffer or have suffered in the past from bipolar disorder (manic depression) or mania
- suffer from eye problems, such as certain types of glaucoma (increased pressure in the eye)
- suffer or have suffered in the past from hepatic dysfunction
- suffer or have suffered in the past from bleeding problems
- suffer from low sodium levels or are at risk of having low sodium levels (for example if you are taking diuretics, particularly if you are elderly)
- suffer from heart problems or high blood pressure or you are taking medicines to lower your blood pressure
- have diabetes (treatment with **Cymbalta** may disrupt the blood sugar balance in some patients)
- suffer from slow gastric emptying
- have a history of drug abuse

Thoughts of suicide and worsening of your depression or anxiety disorder

Depression and other serious psychiatric disorders are known to be the highest risk factors for suicidal tendencies. Nevertheless, in some children, adolescents and young adults who took antidepressants, an increase in suicidal thoughts and actions was observed, particularly at the beginning of treatment, or when the dosage has been changed. If you are depressed and/or have anxiety disorders, you may sometimes have thoughts about harming yourself or committing suicide. These thoughts may appear more frequently when you start taking antidepressants, usually during the first few months of treatment or when the dosage has been changed.

You may be more likely to have such thoughts if:

- you have had thoughts in the past about committing suicide or harming yourself
- you are a young adult. Information collected in clinical trials has shown an increased risk of suicidal behavior in adults below 24 years of age suffering from psychiatric conditions and who have been treated with antidepressants.
- you have (or have a family history of) bipolar disorder (manic-depressive disorder)

Pay attention to every change in mood, behavior, actions, thoughts or feelings, especially sudden changes.

If at any time you have thoughts about harming yourself or committing suicide, call your doctor or go to a hospital immediately. Pay special attention to such changes at the beginning of treatment and after a change in dosage.

The following symptoms have been reported in adults, children and adolescents treated with antidepressants: anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania. Although a causal link between the emergence of such symptoms and the worsening of depression and/or the

emergence of suicidal impulses has not been established, they appear to constitute early signs of suicidal behavior.

It may be helpful to tell a relative or close friend that you are suffering from depression or have an anxiety disorder and ask them to read this leaflet. You can ask them to tell you if they think your depression or anxiety is getting worse, or if they are concerned about changes in your behavior. Also, be sure to attend all appointments with your attending physician.

Patients and their families are advised to closely observe mood and behavioral changes such as increased anxiety, panic attacks, restlessness and agitation, mania or hypomania, aggressiveness or sleep disorders, particularly at the beginning of treatment or when the dosage has been changed. If such changes occur, please contact your doctor immediately. This recommendation must be followed strictly with young patients 18-24 years of age.

Angle Closure Glaucoma

Dilation of the pupils, often caused by antidepressants such as **Cymbalta**, may trigger an angle closure glaucoma attack in patients with anatomically narrow angles who have not undergone iris removal surgery.

Sexual problems (dysfunction)

Talk to your doctor if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with **Cymbalta**. There may be treatments your doctor can suggest.

For additional information on warnings regarding the use of this medicine, see section 4. 'Side effects'.

Use in children and adolescents below 18 years of age

Cymbalta is not intended for the treatment of children and adolescents below 18 years of age.

Drug interactions:

If you are taking, or have recently taken, any other medicines including non-prescription medicines and nutritional supplements, inform your doctor or pharmacist. You should also inform your doctor especially if you are taking:

- other preparations containing duloxetine, such as Yentreve – avoid simultaneous use with this medicine. Check with your doctor whether you are already taking other medicines containing duloxetine.
- Monoamine Oxidase Inhibitors (MAOIs): you should avoid taking **Cymbalta** if you are taking or have recently taken (in the last 14 days), a monoamine oxidase inhibitor (MAOI) drug. Taking an MAOI (such as intravenous methylene blue or linezolid) concomitantly with numerous 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 an MAOI before you can start taking **Cymbalta**. In addition, you must wait at least 5 days after you stop taking **Cymbalta** before you can take an MAOI.
- medicines that increase serotonin levels – these medicines increase the risk of serotonin syndrome (see Chapter 4 "Side effects")
- strong painkillers such as tramadol and fentanyl, meperidine, methadone, or other opioids.
- triptans (for the treatment of migraines)
- tryptophan – an amino acid found in foods, nutritional infusion solutions and food supplements
- tricyclic antidepressants

- St. John's Wort (*Hypericum perforatum*)
- SSRI and SNRI antidepressants
- buspirone
- amphetamines
- lithium

- Medications that affect blood coagulation and clotting, such as:
 - warfarin (coumadin) – if you are taking warfarin, your doctor might monitor your condition at the beginning and at the end of the treatment with **Cymbalta**.
 - nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, naproxen or aspirin. These medicines may increase the risk of bleeding.
- Medicines that affect the central nervous system
- Diuretics
- Medications that lower the level of acidity in the stomach (may cause premature release of the medicine)
- Medicines that lower blood pressure

- **Cymbalta** affects the concentration of other medicines in the blood:
 - theophylline (for asthma treatment)
 - tricyclic antidepressants such as desipramine, nortriptyline, amitriptyline and imipramine
 - phenothiazines
 - medicines for the treatment of cardiac arrhythmia: flecainide and propafenone. Thioridazine, in combination with **Cymbalta** can cause severe heart rhythm problems or sudden death.

- The following medicines affect the concentration of **Cymbalta** in the blood:
 - quinidine for the treatment of arrhythmias
 - fluoxetine, fluvoxamine, paroxetine
 - cimetidine
 - antibacterial medicines from the quinolone family, such as ciprofloxacin or enoxacin

If you experience any unusual symptom while taking any of these medicines concomitantly with **Cymbalta**, you should contact your doctor.

Your doctor should decide if you can take **Cymbalta** together with other medicines. Do not start or stop taking any medication, including medicines purchased without a doctor's prescription and herbal remedies, before consulting your doctor.

Use of this medicine and food

Cymbalta may be taken with or without food.

Use of this medicine and alcohol consumption

Use of **Cymbalta** concomitantly with heavy alcohol intake may be associated with severe liver injury. Avoid heavy alcohol use while taking **Cymbalta**.

Pregnancy and breastfeeding

Consult your doctor or pharmacist before taking any medicine.

- Tell your doctor right away if you are pregnant or think you are pregnant while taking **Cymbalta**. **Cymbalta** may harm your fetus. You should only use **Cymbalta** after discussing with your doctor the potential benefits and any potential risks to your unborn child.

- Make sure that your midwife and/or doctor know that you are being treated with **Cymbalta**. When taking SSRIs and SNRIs, including **Cymbalta**, late in the third trimester, the risk of complications that may require prolonged hospitalization of the newborn, respiratory support and nourishment through a feeding tube, may increase. Such complications can arise immediately upon delivery and can include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability and constant crying. If after birth your baby shows any of the symptoms mentioned above, or if you are concerned about your baby's health, consult your midwife or doctor.
- Tell your doctor if you are breastfeeding or planning to breastfeed. **Cymbalta** passes into breast milk and can be harmful to the baby. Using **Cymbalta** while breastfeeding is not recommended. Consult your doctor about the best way to feed your baby while taking **Cymbalta**.

Driving and using machines

Using this medicine may cause drowsiness or affect your ability to make decisions, think clearly or respond quickly. Therefore, caution should be exercised when driving a vehicle, operating dangerous machinery and any other activity which requires alertness. Do not drive or use any tools or machines until you know how **Cymbalta** affects you.

Important information about some of the ingredients of this medicine

Cymbalta contains sucrose. If your doctor has told you that you have an intolerance to certain types of sugar, consult your doctor before taking this medicine.

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

3. HOW TO USE THIS MEDICINE?

Always use the preparation according to your doctor's instructions. You should check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this preparation.

The dose and manner of treatment will only be determined by your doctor. Your doctor may need to change the dose until he finds the right dose for you. The usual dosage is:

- For diabetic peripheral neuropathic pain:
The usual dose of **Cymbalta** is 60 mg once a day. Your doctor will determine the dose that is appropriate for you.
- For chronic musculoskeletal pain and generalized anxiety disorder:
Most patients will receive 60 mg once daily. Your doctor will determine the dose that is appropriate for you. Some patients require an initial dose of **Cymbalta** 30 mg once daily for one week, and then the usual dose of 60 mg once daily.
- For depression:
Most patients will receive 60 mg once daily. Some patients require an initial dose of **Cymbalta** 30 mg once daily for one week, and then the usual dose of 60 mg once daily.
Elderly - start treatment with an initial dose of 30 mg once daily for two weeks, and only then consider increasing the dose to 60 mg once daily.
- Fibromyalgia:

The initial dose of **Cymbalta** is 30 mg once daily for one week, and then the usual dose of 60 mg once daily.

In most cases, the effect of therapeutic treatment with **Cymbalta** is noticeable after 2-4 weeks of treatment.

Do not exceed the recommended dose.

Cymbalta is intended to be taken orally. You should swallow your capsule whole with a drink of water. **Cymbalta** contains enteric-coated pellets that prevents their dissolution in the stomach. Therefore, do not chew or crush the contents of the capsule and do not open the capsule and sprinkle the contents on food or mix with liquids. This is to prevent the effect of food or drink on the enteric coating. Furthermore, the medicine is not meant to be taken via a nasogastric tube since contents of the capsule may obstruct the tube.

Talk to your doctor about the length of time you should continue taking **Cymbalta**. Do not stop taking **Cymbalta** without talking to your doctor first.

If you accidentally take a higher dose, you should call your doctor or pharmacist immediately. The symptoms of an overdose may include somnolence, coma, serotonin syndrome (a reaction that can cause hallucinations, irritability, coma, rapid pulse, unstable blood pressure, dizziness, sweating, flushing, fever, tremor, muscle rigidity, muscle tightness, hyperreflexia, lack of coordination, nausea, vomiting and diarrhea), seizures, fainting, low blood pressure, high blood pressure, vomiting and rapid heartbeat.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital Emergency Room, and bring the package of the medicine with you.

If you forgot to take the medicine, please take the dose you forgot as soon as you remember. If it is already nearly time for you to take your next dose, skip the one you forgot and only take the next one. Do not take a double dose of **Cymbalta**.

You must persist with the treatment as recommended by your doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor or pharmacist.

If you stop taking the medicine: If your doctor thinks that you no longer need **Cymbalta**, he will instruct you to reduce the dose you are taking gradually before stopping treatment altogether. Do not stop taking this medicine abruptly without consulting your doctor. When you stop taking the medicine too fast or switch from another antidepressant too quickly, you may experience the following severe symptoms: dizziness, headache, nausea, diarrhea, paresthesia (tingling feelings like pins and needles), restlessness and irritability, vomiting, insomnia, anxiety, confusion, emotional instability, hypomania, tinnitus (hearing sounds in the ear when there is no external sound), seizures, excessive perspiration and fatigue.

Do not take medicines in the dark! Check the label and dose each time you take your medicine. Wear glasses if you need them.

If you have additional questions regarding the use of this medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of **Cymbalta** may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Serious Side Effects

- **Suicidal thoughts and actions:**
Contact your doctor immediately if you feel any of the following side effects, especially if they are new, worse, or worry you: suicide attempts, acting on dangerous impulses, acting aggressive, being angry, or violent, thoughts about suicide or dying, new or worse depression, new or worse anxiety, panic attacks, feeling very agitated, restless, new or worse irritability, trouble sleeping, an extreme increase in activity or talking (mania), other unusual changes in behavior or mood.
- **Signs of liver damage:** itching, pain in the upper right side of the abdomen, dark urine, yellowing of the skin or whites of the eyes (jaundice), enlarged liver, sharp increase in liver enzymes. In case of signs of liver damage, contact a doctor immediately.
- **Changes in blood pressure and falls:** Monitor your blood pressure before starting and throughout treatment. **Cymbalta** may increase your blood pressure, decrease your blood pressure when standing and cause dizziness or fainting, mostly when first starting **Cymbalta** or when increasing the dose. **Cymbalta** may increase the risk of falls, especially in elderly.
- **Serotonin syndrome: This condition can be a life-threatening condition.** Symptoms may include: a reaction that can cause changes in mental state (such as irritability, hallucinations, coma), autonomic instability (rapid heart rate, unstable blood pressure, dizziness, excessive sweating, flushing, fever), neuromuscular problems (tremor, rigidity, muscle spasms, hyperreflexia, lack of coordination), seizures, convulsions and/or gastrointestinal symptoms (such as nausea, vomiting, diarrhea). Seek medical attention immediately if you experience these symptoms.
- **Abnormal bleeding:** **Cymbalta** and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin, a non-steroidal anti-inflammatory drugs (NSAIDs), or aspirin. Postpartum bleeding may also be more common.
- **Severe skin reactions:** **Cymbalta** may cause serious skin reactions that may require stopping its use. This may need to be treated in a hospital and may be life-threatening. Call your healthcare provider right away or get emergency help if you have skin blisters, peeling rash, sores in the mouth, hives or any other allergic reactions.
- **Manic episodes:** greatly increased energy, severe trouble sleeping, racing thoughts, reckless behavior, unusually grand ideas, excessive happiness or irritability, talking more or faster than usual.
- **Angle Closure Glaucoma (Visual problems):** eye pain, changes in vision, swelling or redness in or around the eye.
Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.
- **Seizures or convulsions.**
- **Low blood sodium levels** (elderly people may be at greater risk for this): symptoms can include headache, weakness or feeling unsteady, confusion, problems concentrating or thinking or memory problems. More serious symptoms are hallucinations, loss of consciousness, seizures, coma, respiratory failure and death.
- **Problems with urination:** Symptoms may include decreased urine flow, unable to pass any urine.
- **Sexual problems (dysfunction):** Taking serotonin and norepinephrine reuptake inhibitors (SNRIs), including **Cymbalta**, may cause sexual problems.
Symptoms in males may include:
 - delayed ejaculation or inability to have an ejaculation

- decreased sex drive
- problems getting or keeping an erection

Symptoms in females may include:

- decreased sex drive
- delayed orgasm or inability to have an orgasm

Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with **Cymbalta**. There may be treatments your healthcare provider can suggest.

Most Common Adverse Reactions Observed in Adult Clinical Trials

The most commonly observed adverse reactions in **Cymbalta** treated patients (according to the various indications) are:

- Diabetic Peripheral Neuropathic Pain: nausea, somnolence, decreased appetite, constipation, hyperhidrosis, and dry mouth.
- Fibromyalgia: nausea, dry mouth, constipation, somnolence, hyperhidrosis, agitation and decreased appetite.
- Chronic Pain due to Osteoarthritis: nausea, fatigue, constipation, dry mouth, insomnia, somnolence, and dizziness.
- Chronic Low Back Pain: nausea, dry mouth, insomnia, somnolence, constipation, dizziness, and fatigue.

Adverse reactions observed with an incidence of 5% or more relative to the control group in clinical trials in adults:

- nausea
- headache
- dry mouth
- somnolence
- fatigue
- insomnia
- constipation
- dizziness
- diarrhea
- decreased appetite
- hyperhidrosis
- abdominal pain

Adverse reactions observed with an incidence of 2% or more relative to the control group in clinical trials in adults that have major depressive episodes and generalized anxiety disorder:

- **Cardiac Disorders**
Palpitations
- **Eye Disorders**
Vision blurred
- **Gastrointestinal Disorders**
Nausea
Dry mouth
Constipation
Diarrhea
Abdominal pain
Vomiting

- **General Disorders**
Fatigue
- **Metabolism and Nutrition Disorders**
Decreased appetite
- **Nervous System Disorders**
Headache
Dizziness
Somnolence
Tremor
- **Psychiatric Disorders**
Insomnia
Agitation
Anxiety
- **Reproductive System and Breast Disorders**
Erectile dysfunction
Ejaculation delayed
Libido decreased
Orgasm abnormal
- **Respiratory, Thoracic, and Mediastinal Disorders**
Yawning
- **Skin and Subcutaneous Tissue Disorders**
Hyperhidrosis

Adverse reactions observed with an incidence of 2% or more relative to the control group in clinical trials in adults that have neuropathic pain associated with peripheral diabetic neuropathy, fibromyalgia, osteoarthritis and chronic low back pain:

- **Gastrointestinal Disorders**
Nausea
Dry Mouth
Constipation
Diarrhea
Abdominal Pain
Vomiting
Dyspepsia
- **General Disorders**
Fatigue
- **Infections and Infestations**
Nasopharyngitis
Upper Respiratory Tract Infection
Influenza
- **Metabolism and Nutrition Disorders**
Decreased Appetite
- **Musculoskeletal and Connective Tissue**
Musculoskeletal Pain
Muscle Spasms
- **Nervous System Disorders**
Headache
Somnolence
Dizziness
Paraesthesia

- Tremor
- **Psychiatric Disorders**
 - Insomnia
 - Agitation
- **Reproductive System and Breast Disorders**
 - Erectile Dysfunction
 - Ejaculation Disorder
- **Respiratory, Thoracic, and Mediastinal Disorders**
 - Cough
- **Skin and Subcutaneous Tissue Disorders**
 - Hyperhidrosis
- **Vascular Disorders**
 - Flushing
 - Blood pressure increased

Other Adverse Reactions Observed During the Clinical Trial Evaluation of **Cymbalta** in Adults:

- Cardiac Disorders- *Frequent*: palpitations; *Infrequent*: myocardial infarction, fast heart rate (tachycardia), broken heart syndrome (Takotsubo cardiomyopathy).
- Ear and Labyrinth Disorders- *Frequent*: vertigo; *Infrequent*: ear pain and tinnitus.
- Endocrine Disorders- *Infrequent*: hypothyroidism.
- Eye Disorders- *Frequent*: vision blurred; *Infrequent*: double vision (diplopia), dry eye, and visual impairment.
- Gastrointestinal Disorders-*Frequent*: flatulence; *Infrequent*: difficulty swallowing (dysphagia), eructation, gastritis, gastrointestinal hemorrhage, bad smell from the mouth (halitosis), and an inflamed mouth and lips (stomatitis); *Rare*: gastric ulcer.
- General Disorders -*Frequent*: chills/rigors; *Infrequent*: falls, feeling abnormal, feeling hot and/or cold, malaise, and thirst; *Rare*: gait disturbance.
- Infections and Infestations-*Infrequent*: an inflammation of the stomach and intestines (gastroenteritis) and an inflammation of the larynx (laryngitis).
- Investigations-*Frequent*: weight increased, weight decreased; *Infrequent*: blood cholesterol increased.
- Metabolism and Nutrition Disorders- *Infrequent*: dehydration and high blood lipid levels (hyperlipidemia); *Rare*: abnormal levels of blood lipids (dyslipidemia).
- Musculoskeletal and Connective Tissue Disorders-*Frequent*: musculoskeletal pain; *Infrequent*: muscle tightness and muscle twitching.
- Nervous System Disorders- *Frequent*: altered taste perception (dysgeusia), lethargy, and paraesthesia/hypoesthesia; *Infrequent*: disturbance in attention, repetitive and involuntary movements (dyskinesia), involuntary muscle jerks myoclonus, and poor quality sleep; *Rare*: a motor speech disorder (dysarthria).
- Psychiatric Disorders- *Frequent*: abnormal dreams and sleep disorder; *Infrequent*: apathy, bruxism, disorientation/confusional state, irritability, mood swings, and suicide attempt; *Rare*: completed suicide.
- Renal and Urinary Disorders-*Frequent*: urinary frequency; *Infrequent*: dysuria, micturition urgency, nocturia, polyuria, and urine odor abnormal.
- Reproductive System and Breast Disorders- *Frequent*: anorgasmia/orgasm abnormal; *Infrequent*: menopausal symptoms, sexual dysfunction, and testicular pain; *Rare*: menstrual disorder.
- Respiratory, Thoracic and Mediastinal Disorders- *Frequent*: yawning, oropharyngeal pain; *Infrequent*: throat tightness.

- Skin and Subcutaneous Tissue Disorders- *Frequent:* pruritus; *Infrequent:* cold sweat, dermatitis contact, erythema, increased tendency to bruise, night sweats, and photosensitivity reaction; *Rare:* ecchymosis (a type of bruise).
- Vascular Disorders- *Frequent:* hot flush; *Infrequent:* flushing, orthostatic hypotension, and peripheral coldness.

Side effects observed after the beginning of marketing:

acute pancreatitis, anaphylactic reaction, aggression and anger (particularly early in treatment or after treatment discontinuation), angioneurotic edema, angle-closure glaucoma, inflammation of the colon (colitis, microscopic or unspecified), inflamed blood vessel in the skin (cutaneous vasculitis, sometimes associated with systemic involvement), extrapyramidal disorder, spontaneous flow of milk (galactorrhea), gynecological bleeding, hallucinations, high blood glucose (hyperglycemia), high blood prolactin (hyperprolactinemia), hypersensitivity, hypertensive crisis, muscle spasm, rash, restless legs syndrome, seizures upon treatment discontinuation, supraventricular arrhythmia, tinnitus (upon treatment discontinuation), jaw spasm (trismus), and urticaria.

If a side effect appears, if any of the side effects gets worse or if you suffer from a side effect that has not been mentioned in this leaflet, you should consult your doctor.

Reporting of Side Effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects due to drug treatment" that can be found on the Home Page of the Ministry of Health's website (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THIS MEDICINE?

- **Avoid poisoning!** This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiration date refers to the last day of that month.
- **Storage conditions:** store below 25°C.
- 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. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:

sugar spheres, talc, sucrose, hypromellose acetate succinate (HPMCAS), color mixture white DDB8257W, hypromellose 2910 5 cps and triethyl citrate.

Each capsule of **Cymbalta** 30 mg contains 18.1 mg sucrose.

Each capsule of **Cymbalta** 60 mg contains 36.2 mg sucrose.

What Cymbalta looks like and contents of the pack:

Cymbalta is a hard gastro-resistant capsule. Each capsule of **Cymbalta** contains granules of duloxetine hydrochloride with an enteric coating to protect it from stomach acid and prevent its dissolution in the stomach.

Cymbalta is marketed in two dosages: 30 mg and 60 mg.

The 30 mg capsules are blue and white and are imprinted with “30 mg” and the code “9543”.

The 60 mg capsules are blue and green and are imprinted with “60 mg” and the code “9542”.

The **Cymbalta** 30 mg and 60 mg capsules are supplied in packages of 7, 14 and 28 capsules. Not all pack sizes may be marketed.

License holder and address: Eli Lilly Israel Ltd., 4 HaSheizaf St., Ra'anana 4366411

Manufacturer and address: Lilly S.A., Alcobendas, Madrid, Spain

Revised in September 2023 according to MOHs guidelines.

The drug registration numbers in the National Drug Registry in the Ministry of Health:

Cymbalta 30 mg: 132-70-31142-12

Cymbalta 60 mg: 132-71-31143-12