Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Duloxetine Sandoz® 30 mg GRC
Gastro-resistant capsules

Active ingredient:
duloxetine (as hydrochloride) 30 mg

Duloxetine Sandoz® 60 mg GRC
Gastro-resistant capsules

Active ingredient:
duloxetine (as hydrochloride) 60 mg

Inactive ingredients and allergens in this medicine: See *'Important information about some of this medicine's ingredients'* in section 2 and section 6 *'Additional information'*.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

Antidepressants and antianxiety 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 depression, suicidal thoughts, aggressiveness etc.
If changes such as these occur, contact the doctor immediately.

1. What is this medicine intended for?

Duloxetine Sandoz GRC is used to treat adults who have:
- 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: Duloxetine Sandoz GRC belongs to a class of medicines called SNRI and causes an increase in 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 in this medicine (see section 6 *'Additional information'*).
- you have a liver disease.
- you have 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 medicine unless at least 5 days have passed since stopping treatment with Duloxetine Sandoz GRC. See *'Drug interactions'*.
- you are taking thioridazine.

Special warnings about using this medicine:

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

Sexual dysfunction problems
Talk to your doctor if you have any changes in your sexual function, or if you have any questions or concerns about sexual function during treatment with Duloxetine Sandoz GRC. Your doctor may be able to suggest solutions.

Before starting treatment with Duloxetine Sandoz GRC, tell your doctor if you:
- have a kidney disease
- have or have ever had seizures (fits)
- have or have ever had bipolar disorder (manic depression) or mania
- have eye problems, such as certain kinds of glaucoma (increased pressure in the eye)
- have or have ever had impaired liver function or if you consume large quantities of alcohol - excessive alcohol consumption while taking Duloxetine Sandoz GRC may cause liver damage
- have or have ever had abnormal bleeding (a tendency to develop bruises)
- have low sodium levels or are at risk of having low sodium levels (for example if you are taking diuretics, particularly if you are elderly)
- have heart problems or high blood pressure and if you are taking medicines to lower your blood pressure
- have diabetes (treatment with Duloxetine Sandoz GRC may disrupt blood sugar balance in some patients)
- have 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 was changed. If you are depressed and/or have anxiety disorders, you may sometimes have thoughts of 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 under 24 years who have psychiatric conditions and who were treated with antidepressants
- you have (or have a family history of) bipolar disorder (manic-depressive disorder)

Pay attention to any 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, 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 be 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 doctor.

Patients and their families are advised to closely monitor 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, contact your doctor immediately. This recommendation must be followed strictly, particularly with young patients aged 18-24 years.

Use in children and adolescents under 18 years of age
Duloxetine Sandoz GRC is not intended for treating children and adolescents who are under 18 years of age.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly inform your doctor if you are taking:
- other medicines containing duloxetine at different dosages for other indications - avoid using together with this medicine. Check with your doctor whether you are already taking other medicines containing duloxetine.
- monoamine oxidase inhibitors (MAOIs) - avoid taking Duloxetine Sandoz GRC if you are taking or have recently taken (within the last 14 days) a monoamine oxidase inhibitor (MAOI). Taking an MAOI (such as intravenous methylene blue or linezolid) together with many prescription medicines, including Duloxetine Sandoz GRC, 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 Duloxetine Sandoz GRC. Also, you must wait at least 5 days after you stop taking Duloxetine Sandoz GRC before you can take an MAOI.
- medicines that increase serotonin levels - these medicines increase the risk of serotonin syndrome (see Section 4 *'Side effects'*)
- strong painkillers such as tramadol and fentanyl
- triptans (for treating migraine)
- tryptophan - an amino acid found in foods, nutritional infusion solutions and food supplements
- tricyclic antidepressants
- St. John's Wort
- SSRI and SNRI antidepressants
- buspirone
- amphetamines
- lithium

If you experience any unusual symptom while taking any of these medicines together with Duloxetine Sandoz GRC, contact your doctor.

- Medicines 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 end of treatment with Duloxetine Sandoz GRC.
  - non-steroidal 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
- medicines that lower the level of acidity in the stomach (may cause premature release of the medicine)
- medicines that lower blood pressure
- Duloxetine Sandoz GRC 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 arrhythmias: flecainide, propafenone, thioridazine. The combination can cause serious heart rhythm problems or sudden death.
- The following medicines affect the concentration of Duloxetine Sandoz GRC in the blood:
  - quinidine for treating arrhythmias
  - fluoxetine, fluvoxamine, paroxetine
  - cimetidine
  - quinolone antibacterial medicines, such as ciprofloxacin or enoxacin

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

Using this medicine and food
Duloxetine Sandoz GRC may be taken with or without food.

Using this medicine and alcohol consumption
Taking Duloxetine Sandoz GRC concomitantly with heavy alcohol consumption may cause a severe liver injury.

Pregnancy and breastfeeding
Consult your doctor or pharmacist before taking any medicine.
- Tell your doctor right away if you become pregnant or think you are pregnant while taking Duloxetine Sandoz GRC. Duloxetine Sandoz GRC may harm your unborn baby. You should use Duloxetine Sandoz GRC only after discussing the potential benefits and any potential risks to your unborn baby with your doctor.
- Make sure that your midwife and/or doctor know that you are being treated with Duloxetine Sandoz GRC. Taking SSRIs and SNRIs, including Duloxetine Sandoz GRC, late in the third trimester of pregnancy, may increase the risk of complications that may require prolonged hospitalization of the newborn, respiratory support and nourishment through a feeding tube. These complications can develop immediately after delivery and can include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability and persistent crying. If your baby shows any of these symptoms after birth, or if you are concerned about your baby's health, consult your midwife or doctor.
- Tell your doctor if you are breastfeeding or plan to breastfeed. Duloxetine Sandoz GRC passes into breast milk and may be harmful to the baby. Using Duloxetine Sandoz GRC while breastfeeding is not recommended. Consult your doctor about the best way to feed your baby while you are taking Duloxetine Sandoz GRC.

Driving and using machines
Using this medicine may cause drowsiness or affect your ability to make decisions, think clearly or respond quickly. Therefore, using this medicine requires caution 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 Duloxetine Sandoz GRC affects you.

Important information about some of this medicine's ingredients
Duloxetine Sandoz GRC contains lactose, Allura Red AC (E129), sodium, and Sunset Yellow FCF (E110).
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.
This medicine contains Allura Red AC (E129) which may cause allergic reactions.
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium free'.
In addition, Duloxetine Sandoz 60 mg GRC also contains Sunset Yellow FCF (E110) which may cause allergic reactions.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine.
Only your doctor will determine your dosage and how you should take this medicine. Your doctor may need to change your dosage until the right dosage for you is found.
The usual dosage is:
- For diabetic peripheral neuropathic pain:
  The usual dosage of Duloxetine Sandoz GRC is 60 mg once a day. Your doctor will determine the dosage that is right for you.
- For chronic musculoskeletal pain and generalized anxiety disorder:
  Most patients will receive 60 mg once daily. Your doctor will determine the dosage that is right for you. Some patients require an initial dosage of Duloxetine Sandoz 30 mg GRC once daily for one week, and then the usual dosage of 60 mg once daily.
- For depression:
  Most patients will receive 60 mg once daily. Some patients require an initial dosage of Duloxetine Sandoz 30 mg GRC once daily for one week, and then the usual dosage of 60 mg once daily.
  Elderly - start treatment with an initial dosage of 30 mg once daily for two weeks, and only then consider increasing the dosage to 60 mg once daily.
- Fibromyalgia:
  The initial dosage of Duloxetine Sandoz GRC is 30 mg once daily for one week, and then the usual dosage of 60 mg once daily.

In most cases, the effect of Duloxetine Sandoz GRC treatment will be noticeable after 2-4 weeks of treatment.

Do not exceed the recommended dose.

Duloxetine Sandoz GRC is intended to be taken orally. Swallow your capsule whole with water. 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 a beverage.

Talk to your doctor about how long you should continue taking Duloxetine Sandoz GRC. Do not stop taking Duloxetine Sandoz GRC without talking to your doctor first.

If you have accidentally taken a higher dose, call your doctor or pharmacist immediately. The symptoms of an overdose may include sleepiness, coma, serotonin syndrome (a reaction that can cause hallucinations, irritability, coma, rapid heart rate, 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 some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine, please take the missed dose as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and only take the next one.
Do not take a double dose of Duloxetine Sandoz GRC.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine: If your doctor thinks that you no longer need Duloxetine Sandoz GRC, they will instruct you to gradually reduce the dosage you are taking before stopping treatment altogether. Do not stop taking this medicine abruptly without consulting your doctor. If you stop taking this medicine too fast or switch from another antidepressant too quickly you may experience the following severe symptoms: dizziness, headache, nausea, diarrhea, paresthesia (pins and needles), restlessness and irritability, vomiting, insomnia, anxiety, confusion, feeling emotionally unstable, hypomania, tinnitus (hearing ringing in your ear when there is no external sound), seizures, excessive sweating, and fatigue.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult a doctor or pharmacist.

4. Side effects

Like with any medicine, using Duloxetine Sandoz GRC may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Severe side effects
- 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.
- Severe skin reactions: Duloxetine Sandoz GRC may cause serious skin reactions that may require stopping its use. This may need to be treated in the hospital and may be life-threatening. Contact your doctor or emergency medical service right away if you have skin blisters, peeling skin rash, sores in the mouth, hives or any other allergic reactions.
- Suicidal thoughts and actions
  Contact your doctor immediately if you feel any of the following side effects, especially if they are new, get worse, or worry you:
  Suicide attempts, dangerous impulses, aggression, anger, violence, thoughts about suicide or dying, new or worsening depression, new or worsening anxiety, panic attacks, feeling very agitated, restlessness, new or worsening irritability, sleeping problems, extreme increase in activity or talking (mania), other changes in behavior or mood.
- serotonin syndrome: a potentially life-threatening condition. Symptoms may include: a reaction that can cause a feeling of 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 and/or gastrointestinal symptoms (such as nausea, vomiting, diarrhea). Seek medical attention immediately if you experience these symptoms.
- changes in blood pressure and falls: monitor your blood pressure before starting and throughout treatment. Duloxetine Sandoz GRC may increase your blood pressure, decrease your blood pressure when standing and cause dizziness or fainting, mostly when first starting to take Duloxetine Sandoz GRC or when increasing the dosage. Duloxetine Sandoz GRC may increase the risk of falls, especially in the elderly.
- abnormal bleeding: Duloxetine Sandoz GRC and other antidepressant medicines may increase the risk of bleeding and bruising, especially if you are also taking a blood thinner such as warfarin, non-steroidal anti-inflammatory drugs (NSAIDs) or aspirin. Postpartum bleeding may also be more common.
- manic episodes: greatly increased energy, severe trouble sleeping, racing thoughts, reckless behavior, unusually grand ideas, excessive irritability or happiness, talking more or faster than usual.
- visual problems: eye pain, changes in vision, swelling or redness in or around the eye.
  Only some people are at risk for these side effects. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.
- seizures and convulsions
- low blood sodium levels: elderly people are at a greater risk for this. Symptoms can include headache, weakness or feeling unsteady, confusion, difficulty concentrating, 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 dysfunction:
  Taking serotonin and norepinephrine reuptake inhibitors (SNRIs), including Duloxetine Sandoz GRC, may cause sexual problems.

  Symptoms in men may include:
  - delayed ejaculation or inability to have an ejaculation
  - decreased sex drive
  - problems getting or keeping an erection

  Symptoms in women may include:
  - decreased sex drive
  - delayed orgasm or inability to have an orgasm

  Talk to your doctor if you experience any changes in your sexual function or if you have any questions or concerns regarding your sexual function during treatment with Duloxetine Sandoz GRC. There may be solutions your doctor can suggest.

Most common side effects in adults observed in clinical trials
The most commonly observed side effects observed in Duloxetine-treated adults (according to the various indications) are:
- Diabetic peripheral neuropathic pain – nausea, somnolence, decreased appetite, constipation, excessive sweating and dry mouth.
- Fibromyalgia – nausea, dry mouth, constipation, somnolence, excessive sweating, agitation, 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.

Side effects 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, excessive sweating, abdominal pain

Side effects observed with an incidence of 2% or more relative to the control group in clinical trials in adults who have major depressive episodes and generalized anxiety disorder:
- Cardiac Disorders – palpitations
- Eye Disorders – blurred vision
- 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, delayed ejaculation, libido decreased, abnormal orgasm
- Respiratory and Thoracic Disorders – yawning
- Skin Disorders – excessive sweating

Side effects observed with an incidence of 2% or more relative to the control group in clinical trials in adults who 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, indigestion
- General Disorders – fatigue
- Infections and Infestations – nasopharyngitis, upper respiratory tract infections, influenza
- Metabolism and Nutrition Disorders – decreased appetite
- Musculoskeletal and Connective Tissue – musculoskeletal pain, muscle spasms
- Nervous System Disorders – headache, somnolence, dizziness, paraesthesia (abnormal sensation of the skin), tremor
- Psychiatric Disorders – insomnia, agitation
- Reproductive System and Breast Disorders – erectile dysfunction, ejaculation disorders
- Respiratory and Thoracic Disorders – cough
- Skin Disorders – excessive sweating
- Vascular Disorders – flushing, blood pressure increased

Other side effects observed during the clinical trial evaluation of Duloxetine 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.
- Vision Disorders – *Frequent:* blurred vision. *Infrequent:* double vision (diplopia), dry eye, and visual impairments.
- Gastrointestinal Disorders – *Frequent:* flatulence. *Infrequent:* difficulty swallowing (dysphagia), belching, gastritis, gastrointestinal hemorrhage, bad smell from the mouth (halitosis), an inflamed mouth and lips (stomatitis). *Rare:* gastric ulcers.
- General Disorders – *Frequent:* chills. *Infrequent:* falls, feeling abnormal, feeling hot and/or cold, malaise and thirst. *Rare:* gait disturbance.
- Infections and Infestations – *Infrequent:* inflammation of the stomach and intestines (gastroenteritis) and inflammation of the larynx (laryngitis).
- Additional Investigations – *Frequent:* weight increased, weight decreased. *Infrequent:* blood cholesterol increased.
- Metabolism and Nutrition Disorders – *Infrequent:* dehydration and high blood lipid levels (hyperlipidemia). *Rare:* blood lipids imbalance (dyslipidemia).
- Musculoskeletal and Connective Tissue Disorders – *Frequent:* musculoskeletal pain. *Infrequent:* muscle tightness and muscle twitching.
- Nervous System Disorders – *Frequent:* altered taste perception, lethargy, and paraesthesia/hypoesthesia. *Infrequent:* disturbance in attention, repetitive and involuntary movements (dyskinesia), involuntary muscle jerks (myoclonus) and poor quality sleep. *Rare:* speech disorder (dysarthria).
- Psychiatric Disorders – *Frequent:* abnormal dreams and sleep disorders. *Infrequent:* apathy, bruxism, disorientation/confusion, irritability, mood swings and suicide attempts. *Rare:* suicide.
- Renal and Urinary Disorders – *Frequent:* urinary frequency. *Infrequent:* dysuria, micturition urgency, nocturia, polyuria, and abnormal urine odor.
- Reproductive System and Breast Disorders – *Frequent:* anorgasmia/abnormal orgasm. *Infrequent:* menopausal symptoms, sexual dysfunction and testicular pain. *Rare:* menstrual disorder.
- Respiratory and Thoracic Disorders – *Frequent:* yawning, oropharyngeal pain. *Infrequent:* throat tightness.
- Skin and Skin Tissue Disorders – *Frequent:* pruritus. *Infrequent:* cold sweat, contact dermatitis, erythema, increased tendency to bruise, night sweats, and photosensitivity reaction. *Rare:* ecchymosis (a type of bruise).
- Vascular Disorders – *Frequent:* hot flushes. *Infrequent:* flushing, orthostatic hypotension, and peripheral coldness.

Side effects observed after the beginning of marketing:
acute pancreatitis, anaphylactic shock, aggression and anger (particularly in early stages of treatment or after treatment discontinuation), edema of the face, oral cavity, stomach and limbs (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 you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by clicking the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store this medicine?

- **Avoid poisoning!** To avoid poisoning, keep this, and any other medicine, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** do not store above 25°C.
- Do not discard medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. This will help protect the environment.

6. Additional information

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

Capsule content:
microcrystalline cellulose (type 102), hypromellose acetate succinate, povidone, starch maize pregelatinised, titanium dioxide (E171), lactose monohydrate, HPMC 2910/hypromellose 15cP, 3cP, 50cP (E464), macrogol/PEG MW 4000 (E1521), talc, magnesium stearate, sodium stearyl fumarate.
Capsule shell:
gelatin, titanium dioxide (E171), Brilliant Blue FCF (FD&C Blue No. 1, E133), Allura Red AC (FD&C Red No.40, E129)
The capsule shell of Duloxetine Sandoz 60 mg GRC also contains the following:
Sunset Yellow FCF (FD&C Yellow No.6, E110), Quinoline Yellow (E104).
Imprinting ink:
shellac glaze~45% (20% esterified) in ethanol, FD&C blue#2 indigo carmine aluminum lake (E132), N-butyl alcohol, titanium dioxide (E171), propylene glycol (E1520), isopropyl alcohol.

Each capsule of **Duloxetine Sandoz 30 mg GRC** contains 1.95 mg lactose monohydrate.
Each capsule of **Duloxetine Sandoz 60 mg GRC** contains 3.9 mg lactose monohydrate.

What the medicine looks like and contents of the pack:
Duloxetine Sandoz GRC is a gastro-resistant hard gelatin capsule.

Duloxetine Sandoz GRC is marketed in two strengths, 30 mg and 60 mg.

Duloxetine Sandoz 30 mg GRC capsules
Opaque dark blue cap and opaque white body, size 2, imprinted with "30". Each capsule contains 4 white to off-white, round, bi-convex mini tablets.

Duloxetine Sandoz 60 mg GRC capsules
Opaque dark blue cap and opaque yellowish-green body, size 0E, imprinted with "60". Each capsule contains 8 white to off-white, round, bi-convex mini tablets.

Duloxetine Sandoz 30 mg and 60 mg GRC capsules are supplied in packs of 30, 28, 14, 7 capsules.
Not all pack sizes may be marketed.

License holder and importer's name and address: Novartis Israel Ltd., P.O.Box 7126, Tel-Aviv.

Revised in February 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Duloxetine Sandoz® 30 mg GRC: 167-67-35796-00
Duloxetine Sandoz® 60 mg GRC: 167-68-35797-00