## (Preparations) - 1986

## **Duloxetine Sandoz®** 30 mg GRC

Gastro-resistant capsules

Active ingredient: duloxetine 30 mg (as hydrochloride)

## 60 mg GRC Gastro-resistant capsules

Duloxetine Sandoz®

Active ingredient:

duloxetine 60 mg (as hydrochloride)

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

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:
- generalized anxiety disorder (chronic feeling of anxiety or nervousness) neuropathic pain associated with peripheral diabetic neuropathy
- chronic musculoskeletal pain, when other treatment cannot be administered or previous treatment has failed Therapeutic group: Duloxetine Sandoz GRC belongs to the SNRI family of

drugs 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. Before starting treatment with Duloxetine Sandoz GRC, tell your doctor

#### if you: are breastfeeding

are pregnant or trying to become pregnant while taking Duloxetine Sandoz

in the eye)

- GRC have a severe kidney disease
- have ever had seizures (fits)
- have ever had bipolar disorder (manic depression) or mania • have eye problems, such as certain kinds of glaucoma (increased pressure
- 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 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

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

- · you are a young adult. Information collected in clinical trials has shown an increased risk of suicidal behavior in adults aged less than 24 years who
- have psychiatric conditions and who were treated with antidepressants you have (or have a family history of) bipolar disorder (manic-depression) 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

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 constitute early signs of suicidal behavior. It may be helpful to tell a relative or close friend that you are suffering from

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,

depression or have an anxiety disorder and ask them to read this leaflet. You

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 the 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 a MAOI (such as intravenous

methylene blue or linezolid) together with many prescription medicines, including Duloxetine Sandoz GRC, can cause serious or even lifethreatening side effects. You must wait at least 14 days after you have stopped taking a 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 a 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
- If you experience any unusual symptom while taking any of these medicines together with Duloxetine Sandoz GRC, you should contact your doctor.

lithium

Medicines that affect blood coagulation and clotting such as:

- warfarin (coumadin) patients taking warfarin should be monitored 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
- 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

• quinolone antibacterial medicines, such as: ciprofloxacin or enoxacin

- · quinidine for treating arrhythmias fluoxetine, fluvoxamine, paroxetine

- This medicine is dispensed with a doctor's prescription only
- Your doctor should decide if you can take Duloxetine Sandoz GRC together with other medicines. Do not start or stop taking any medicines, including medicines purchased without a doctor 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

Do not consume large quantities of alcohol while taking Duloxetine Sandoz GRC, as this may damage your liver.

## 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, 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 after birth your baby shows any of these symptoms, 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 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 Only your doctor will determine the 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

Fibromyalgia:

- 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.
- 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 a drink of 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 liquids

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

If you stop taking this medicine: If your doctor thinks that you no longer need Duloxetine Sandoz GRC, he will instruct you to gradually reduce the dose you are taking before stopping treatment altogether. Do not stop taking 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, 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

4. Side effects

# Like with any medicine, using Duloxetine Sandoz GRC may cause side

consulting your doctor.

effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them. You must stop the treatment and contact your doctor immediately if the following reactions develop:

• Signs of liver damage: itching, dark urine, pain in the upper right side of

- the abdomen, yellowing of the skin or whites of the eyes (jaundice), sharp increase in liver enzymes. In patients who develop jaundice or any other symptom indicating liver dysfunction - treatment with Duloxetine Sandoz GRC has to be discontinued. Severe allergic reaction that causes blisters, rash with peeling skin, mouth sores, urticaria, or other signs of hypersensitivity - treatment with Duloxetine
- Sandoz GRC has to be discontinued immediately with the appearance of these symptoms, as there is a risk of Stevens Johnson syndrome. 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, violencethoughts of suicide or dying
- new or worsening depressionnew or worsening anxiety
- panic attacks feeling very agitated, restlessness · new or worsening irritability
- sleeping problems extreme increase in activity or talking (mania) other unusual changes in behavior or mood
- serotonin syndrome: a possibly 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, convulsions and/or gastrointestinal symptoms (such as nausea, vomiting, diarrhea). abnormal bleeding: SSRI and SNRIs, including Duloxetine Sandoz GRC, can increase the risk of bleeding such as subcutaneous hematomas (which may also appear as red dots on the skin), nose bleeds, and even
- life-threatening bleeding, 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 low blood sodium levels (especially in the elderly or patients taking diuretics): symptoms can include headache, difficulty concentrating, memory problems, confusion, weakness, instability that can lead to falls. More serious symptoms
- and death. hypotension when transitioning from a lying to standing position, which causes dizziness, falls or fainting, especially at the beginning of treatment or after the dose is increased. Blood pressure should be monitored before and during treatment. The falls may be related to hypotension as well as other factors
- Very common side effects (may affect more than 1 in 10 users) headache, sleepiness nausea, dry mouth Common side effects (may affect 1-10 in 100 users)
- lack of appetite • sleep disorders, insomnia, restlessness, anxiety, difficulty or inability to experience orgasm, abnormal dreams
- dizziness, chills, paresthesia (pricking or tingling of the skin) blurred vision
- feeling the heart pumping in the chest (palpitations) · increased blood pressure, hot flashes

• increased tendency to yawn

- constipation, flatulence, diarrhea, abdominal pain, abdominal discomfort, abdominal tenderness, vomiting, digestive disorder
  - increased sweating, rash (itchy)
  - muscle pain, muscle spasm, back pain

  - · frequent urination
  - fatigue · weight loss or gain · pain in the pharynx

throat tightness

- changes in the sense of taste • feeling of dizziness or "spinning" (vertigo)
- restlessness
- decrease in urine flow
- Uncommon side effects (may affect 1-10 in 1,000 users) throat inflammation that causes hoarseness
- suicidal thoughts, teeth grinding, feeling confused, apathy, spatial disorientation sudden involuntary movements, feeling restless or unable to sit or stand
- calmly, irritability, difficulty concentrating, lack of coordination, restless legs syndrome, poor quality sleep, mood swings, suicide attempts
- vision problems, dry eyes, double vision, dilation of the pupils (mydriasis) ear pain, tinnitus (hearing sounds in the ear when there is no external sound)
- rapid or unstable pulse
- fainting, feeling faint, or fainting when standing up, cold fingers and/or toes
   gastrointestinal inflammations, gastrointestinal bleeding
- night sweats, rash, allergic inflammation of the skin, redness, cold sweat, sensitivity to sunlight, increased tendency to bruise muscle rigidity, muscle spasms • difficulty or inability to pass urine, painful urination, urgent urination, needing
- to pass more urine than usual, unusual urine odor, nocturia (passing urine during the night)
- pain in the testicles sexual dysfunction decreased sex drive
- a sharp drop in blood pressure when switching from lying down to sitting or from sitting to standing (especially at the beginning of treatment or after
- increasing the dose) increased risk of falls (especially in the elderly), feeling sick, thirst, tremor, feeling hot and/or cold
- flu
- upper respiratory tract infection

· decreased thyroid gland activity

not been established yet)

acute pancreatitis

- difficulties with swallowing
   Duloxetine Sandoz GRC may cause side effects that you are not aware of, such as an increase in blood levels of lipids (hyperlipidemia) or cholesterol
- dehydration • bad breath, inflammation of the mouth
- menopausal symptomsmyocardial infarction broken-heart syndrome (Takotsubo cardiomyopathy)
- Rare side effects (may affect 1-10 in 10,000 users) stomach ulcer menstrual disorders
- increase or decrease in blood lipid levels (dyslipidemia) speech disorders • subcutaneous hematomas (which may also appear as red dots on the skin)
- suicide Side effects of unknown frequency (the frequency of these effects has
- anaphylactic reaction • aggression and anger (especially at the beginning or after treatment is stopped)
- or throat extrapyramidal disorder secretion of milk from the breast (galactorrhea), high prolactin levels

• angioedema - a severe allergic reaction that can cause swelling of the face

- increased intraocular pressure (narrow-angle glaucoma) pain in the eyes, vision change, swelling or redness around/inside the eye
   cutaneous vasculitis (sometimes with systemic involvement)
- gynecological bleedinghallucinations
- · high blood pressure crisis colitis - microscopic or unspecified
- muscle spasms convulsions when treatment is stopped change in heart rate - arrhythmia

• high blood sugar levels (hyperglycemia)

- tinnitus (when treatment is discontinued) · spasms of the jaw muscles
- urticaria tremor

hypersensitivity

- vomiting
- nasopharyngitis • Duloxetine Sandoz GRC may cause symptoms that you are not aware of, such as an increase in liver enzymes, bicarbonate, sugar, as well as an increase or decrease in blood potassium levels

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

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

Side effects can be reported to the Ministry of Health by clicking the link

# 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.

pharmacist how to dispose of medicines you no longer use. This will help

• Storage conditions: do not store above 25°C. Do not discard medicines via wastewater or household waste. Ask your

## protect the environment. 6. Additional information

Capsule shell:

In addition to the active ingredient, this medicine also contains the following inactive ingredients: 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.

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).

Each capsule of Duloxetine Sandoz 30 mg GRC contains 1.95 mg lactose monohydrate

monohydrate

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.

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

Registration number of the medicine in the Ministry of Health's National Duloxetine Sandoz® 30 mg GRC: 167-67-35796-00 Duloxetine Sandoz® 60 mg GRC: 167-68-35797-00

30, 28, 14, 7 capsules

Not all pack sizes may be marketed

are hallucinations, loss of consciousness, seizures, coma, respiratory failure

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Each capsule of Duloxetine Sandoz 60 mg GRC contains 3.9 mg lactose What the medicine looks like and contents of the pack: Duloxetine Sandoz GRC is a gastro-resistant hard gelatin capsule

P.O.Box 7126, Tel-Aviv. Revised in July 2021 according to MOH guidelines

License holder and importer's name and address: Novartis Israel Ltd.,

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