Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Dulox Teva 30 mg

Gastro-resistant capsules

Active ingredient:

Each capsule contains:

Duloxetine (as hydrochloride) 30 mg

Dulox Teva 60 mg

Gastro-resistant capsules

Active ingredient:

Each capsule contains:

Duloxetine (as hydrochloride) 60 mg

Inactive ingredients and allergens in the preparation: See section 2 under 'Important information about some of this medicine's ingredients', 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 of depression, suicidal thoughts, aggressiveness, etc.
If changes such as these occur, contact the doctor immediately.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Dulox Teva 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 treatment cannot be administered or previous treatment has failed. This indication has been established in studies in patients with chronic low back pain (CLBP) and chronic pain due to osteoarthritis.

Therapeutic group: Dulox Teva 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 that this medicine contains (see section 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 Dulox Teva; see 'Interactions with other medicines'.
- You are taking thioridazine.

Special warnings regarding use of this medicine

Before starting treatment with Dulox Teva, 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 Dulox Teva 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).

Please 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, 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 doctor.

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, contact your doctor immediately. This recommendation must be followed strictly with young patients aged 18-24 years of age.

Angle closure glaucoma – Dilation of the pupils, often caused by antidepressants such as Dulox Teva, 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 function during treatment with Dulox Teva. 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
Dulox Teva is not intended for the treatment of children and adolescents below 18 years of age.

Interactions with other medicines
If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Especially, inform your doctor or pharmacist if you are taking:

- other preparations containing duloxetine. Avoid simultaneous use with this medicine. Check with your doctor if you are taking other medicines containing duloxetine.
- monoamine oxidase inhibitors (MAOIs) – you should avoid taking Dulox Teva 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 Dulox Teva, 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 Dulox Teva. In addition, you must wait at least 5 days after you stop taking Dulox Teva before you can take an MAOI.
- medicines that increase serotonin levels – these medicines increase the risk of serotonin syndrome (see section 4 'Side effects') ● SSRI and SNRI antidepressants ● tricyclic antidepressants
- strong painkillers such as tramadol, 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
- *Hypericum perforatum* (St. John's wort)
- 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 end of treatment with Dulox Teva.
  - 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 Dulox Teva and reduce its efficacy)
- Medicines that lower blood pressure

- Dulox Teva 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, propafenone.
    Thioridazine, the combination can cause severe heart rhythm problems or sudden death.

- The following medicines affect the concentration of Dulox Teva 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 reaction while taking any of the above medicines concomitantly with Dulox Teva, you should contact your doctor.

Your doctor should decide if you can take Dulox Teva 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.

Using this medicine and food
Dulox Teva may be taken with or without food.

Using this medicine and alcohol consumption
Taking Dulox Teva concomitantly with heavy alcohol intake may cause severe liver injury. Avoid heavy alcohol consumption while taking Dulox Teva.

Pregnancy and breastfeeding
Consult your doctor or pharmacist before taking any medicine.
- Tell your doctor right away if you are pregnant or if you think you are pregnant while taking Dulox Teva. Dulox Teva may harm your unborn baby. You should only use Dulox Teva after discussing the potential benefits and any potential risks to your unborn child with your doctor.
- Make sure that your midwife and/or doctor know that you are being treated with Dulox Teva. When taking SSRIs and SNRIs, including Dulox Teva, 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. Dulox Teva passes into breast milk and can be harmful to the baby. Using Dulox Teva while breastfeeding is not recommended. Consult your doctor about the best way to feed your baby while taking Dulox Teva.

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 Dulox Teva affects you.

Important information about some of this medicine's ingredients
Dulox Teva 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.

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 dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine. Your doctor may need to change the dose until finding the right dose for you. The recommended dose is:
- **For diabetic peripheral neuropathic pain:** the usual dose of Dulox Teva 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 Dulox Teva 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 Dulox Teva 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 Dulox Teva is 30 mg once daily for one week, and then the usual dose of 60 mg once daily.

In most cases, the effect of medication therapy with Dulox Teva is noticeable after 2-4 weeks of treatment.

Do not exceed the recommended dose.

Direction for use
Dulox Teva is intended to be taken orally.
You should swallow the capsule whole with water. Dulox Teva contains enteric-coated pellets that prevent 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 in beverages. 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 Dulox Teva. Do not stop taking Dulox Teva 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 some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine, please take the dose you forgot as soon as you remember. However, 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 Dulox Teva.
Follow 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 this medicine: If your doctor thinks that you no longer need Dulox Teva, they 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 <u>every time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>SIDE EFFECTS</u>

As with any medicine, using Dulox Teva may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Severe 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. Dulox Teva may increase your blood pressure or decrease your blood pressure when standing and cause dizziness or fainting, mostly when first starting Dulox Teva or when increasing the dose. Dulox Teva may increase the risk of falls, especially in the 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), convulsions and/or gastrointestinal symptoms (such as nausea, vomiting, diarrhea). Seek medical attention immediately if you experience these symptoms.
- **Abnormal bleeding** – Dulox Teva 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.
- **Severe skin reactions** – Dulox Teva may cause serious skin reactions that may require stopping its use. These effects may need to be treated in a hospital and may be life-threatening. Contact your doctor right away or get emergency medical 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 (vision 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 or convulsions**
- **Low blood sodium levels** – (elderly people may be at greater risk for this): symptoms can include headache, weakness or instability, 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** – the symptoms may include decreased urine flow, unable to pass any urine.
- **Sexual dysfunction** –Taking serotonin and norepinephrine reuptake inhibitors (SNRIs), including Dulox Teva, may cause sexual dysfunction.
  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 develop any changes in your sexual function or if you have any questions or concerns about sexual function during treatment with Dulox Teva. There may be treatments your doctor can suggest.

Most Common Side Effects Observed in Adult Trials
The most commonly observed adverse reactions in Dulox Teva 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, 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; hyperhidrosis; abdominal pain

Side effects 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, anxieties ● **Reproductive System and Breast Disorders** – erectile dysfunction, delayed ejaculation, decreased libido, abnormal orgasm ● **Respiratory and Thoracic Disorders** – yawning ● **Skin and Subcutaneous Tissue Disorders** – hyperhidrosis

Side effects 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 infections, influenza ● **Metabolism and Nutrition Disorders** – decreased appetite ● **Musculoskeletal and Connective Tissue** – musculoskeletal pain, muscle spasms ● **Nervous System Disorders** – headache, somnolence, dizziness, paresthesia, tremor ● **Psychiatric Disorders** – insomnia, agitation ● **Reproductive System and Breast Disorders** – erectile dysfunction, ejaculation disorder ● **Respiratory and Thoracic Disorders** – cough ● **Skin and Subcutaneous Tissue Disorders** – hyperhidrosis ● **Vascular Disorders** – flushing, blood pressure increased

Other Side Effects Observed During the Clinical Trial Evaluation of Duloxetine in Adults:
● **Cardiac Disorders** – Frequent: palpitations/heart throbbing. Infrequent: myocardial infarction, fast heart rate, 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, dry eye, and visual impairment ● **Gastrointestinal Disorders** – Frequent: flatulence. Infrequent: difficulty swallowing, eructation, gastritis, gastrointestinal hemorrhage, bad smell from the mouth, and an inflamed mouth and lips. 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: an inflammation of the stomach and intestines and an inflammation of the larynx ● **Additional Tests** – Frequent: weight gain, weight loss. Infrequent: elevated blood cholesterol ● **Metabolism and Nutrition Disorders** – Infrequent: dehydration and high blood lipid levels. Rare: imbalance of blood lipids ● **Musculoskeletal and Connective Tissue Disorders** – Frequent: musculoskeletal pain; Infrequent: muscle tightness and muscle twitching ● **Nervous System Disorders** – Frequent: altered taste perception, lethargy, paresthesia/hypoesthesia. Infrequent: disturbance in attention, repetitive and involuntary movements (dyskinesia), involuntary muscle jerks, and poor quality sleep. Rare: inability to speak (dysarthria) ● **Psychiatric Disorders** – Frequent: abnormal dreams and sleep disorders. Infrequent: apathy, bruxism, disorientation/confusional state, irritability, mood swings, and suicide attempt. Rare: 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/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 Subcutaneous Tissue Disorders** – Frequent: pruritus. Infrequent: cold sweat, contact dermatitis, erythema, increased tendency to bruise, night sweats, and photosensitivity. 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 early in treatment or after treatment discontinuation), edema in the face, mouth, stomach and limbs, 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 disorders, spontaneous flow of milk (galactorrhea), gynecological bleeding, hallucinations, high blood glucose levels (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.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found 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?

- **Prevent poisoning!** This and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order 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) which appears on the package. The expiration date refers to the last day of that month.
- **Store below 25°C.**
- Do not dispose of any medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains the following inactive ingredients:
Sugar spheres, hypromellose phthalate, hypromellose, triethyl citrate, hydroxypropylcellulose, talc, titanium dioxide, black iron oxide (E172), imprinting ink black.

Dulox Teva 30 mg also contains the ingredient brilliant blue FCF – FD&C blue 1 (E133).

What the medicine looks like and contents of the package
Dulox Teva is a gastro-resistant capsule. Each capsule of **Dulox Teva** contains granules of duloxetine hydrochloride with an enteric coating to protect it from stomach acid and prevent its dissolution in the stomach.
Dulox Teva 30 mg: A capsule with blue opaque cap and grey opaque body. The capsule is marked with DLX 30.
Dulox Teva 60 mg: A capsule with white opaque cap and grey opaque body. The capsule is marked with DLX 60.

Dulox Teva 30 mg and Dulox Teva 60 mg are packed in a blister (tray). The package contains 7, 10, 14, 28, 30, 56 or 100 capsules. Not all package sizes may be marketed.

Manufacturer and license holder:
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

This leaflet was revised in November 2023.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Dulox Teva 30 mg: 166-98-35976 **Dulox Teva 60 mg:** 166-99-36004

For a printed patient leaflet in English, please contact the product's license holder by email Tevacare@med-trix.com or by phone at 1-800-805-005