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PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE REGULATIONS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Duloxetine DR Teva® 30 mg Capsules

The active ingredient and its quantity:
Each capsule contains:
Duloxetine 30 mg (as HCl)

For the list of inactive ingredients, please see section 6.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. They may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- This medicine is intended for the treatment of depression, treatment of neuropathic pain associated with peripheral diabetic neuropathy, treatment of generalized anxiety, treatment of fibromyalgia and treatment of chronic muscle pain if a different treatment cannot be given or if a previous treatment has failed.

Therapeutic group:
Serotonin-norepinephrine reuptake inhibitors (SNRIs).

2. BEFORE USING THE MEDICINE:

Do not use this preparation if:

- you are sensitive to duloxetine or to any of the other ingredients included in this medicine (see section 6).
- you are suffering from impaired function of the liver or from a severe kidney disease.
- you are taking other medicines that contain duloxetine.
- Do not use this medicine concomitantly or within 14 days of administering monoamine oxidase inhibitors (MAOIs)-type medicines for the treatment of depression.
- Do not start taking MAOIs-type medicines for the treatment of depression, if at least 5 days have not passed from discontinuing treatment with Duloxetine DR Teva®.
- Do not use this medicine concomitantly with fluvoxamine for the treatment of depression; quinolone antibiotics, such as ciprofloxacin or enoxacin; thioridazine.
- Do not use this medicine if you are suffering from uncontrolled, closed-angle glaucoma.

Special warnings regarding use of the medicine:
This medicine is not usually intended for use in children and adolescents below the age of 18. Nonetheless, your doctor may prescribe this medicine for you even if you are below the age of 18, when he thinks that it is for your benefit. The doctor prescribed this medicine for you and you are interested in talking to him – refer to the doctor again. You should be aware that there is increased risk for occurrence of side effects among patients below the age of 18, such as: attempted suicidal thoughts and hostility (predominantly aggression, anger and opposition) when taking medicines of this kind. In addition, there are no data regarding the long-term safety effects with regard to growth and development, maturation, cognitive behavior and behavioral development in children and adolescents.
- Depression and other severe psychiatric disorders are known as the highest risk factors for suicide. An increase in suicidal thoughts and actions has been observed in some children, adolescents and young adults (below the age of 25 years) who took antidepressants, particularly at the beginning of the treatment.
It is recommended that patients and their family members monitor mood and behavior changes, such as: increased depression or anxiety and the occurrence of suicidal thoughts, restlessness, aggressiveness or other abnormal changes, especially the beginning of the treatment or when the dosage is changed. If changes of this sort occur, refer to a doctor immediately. **This recommendation should be more strictly adhered to in young patients aged 18-24.**
Do not abruptly stop taking this medicine without consulting a doctor.

Before treatment with Duloxetine DR Teva®, tell the doctor if:
- you are suffering, or have suffered in the past, from mania or bipolar affective disorder and/or convulsions.
- you are suffering, or have suffered in the past, from impaired function of: the heart and/or high blood pressure – refer to patients, it is recommended to monitor blood pressure before beginning and during the course of treatment; the eyes (e.g. glaucoma – increased intraocular pressure), the liver or if you consume large quantities of alcohol – high alcohol consumption concomitant to taking duloxetine may harm the liver; the kidney/urinary system.
- you have a history of bleeding (tendency to develop bruises).
- you are at risk of low sodium levels (e.g., if you are taking diuretics, especially if you are elderly). you are being treated with another medicine that may cause liver damage or if you are taking another medicine to treat depression.
- you are pregnant or are planning to become pregnant or are breastfeeding.
- you are taking the herb *Hypericum* (St. John's Wort).

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:
- Other medicines containing duloxetine – avoid taking concomitantly with Duloxetine DR Teva®.
- Medicines that cause sleepiness/drowsiness, including: morphine (e.g., ventalfasol), monoamine oxidase inhibitors (MAOIs)-type medicines (e.g., moclobemide), linezolid, tricyclic antidepressants (e.g., nortriptyline, amitriptyline, imipramine, desipramine, clomipramine), pethidine, the *Hypericum* herb (St. John's Wort). These medicines increase the risk of side effects, including serotonin syndrome (see section 4 – Side effects).
- Cimetidine.
- Medicines that raise serotonin level: medicines from the triptans family (for treatment of migraine), tramadol, tryptophan (an amino acid present in foods, parenteral nutrition solutions, and food supplements), medicines that affect the central nervous system, medicines for treatment of depression: medicines of the SSRIs type (e.g., paroxetine, fluvoxamine), medicines of the SNRIs type (e.g., venlafaxine), monoamine oxidase inhibitors (MAOIs)-type medicines (e.g., moclobemide), linezolid, tricyclic antidepressants (e.g., nortriptyline, amitriptyline, imipramine, desipramine, clomipramine), pethidine, the *Hypericum* herb (St. John's Wort). These medicines increase the risk of side effects, including serotonin syndrome (see section 4 – Side effects).
- Diuretics.
- Medicines that raise serotonin level: medicines from the triptans family (for treatment of migraine), tramadol, tryptophan (an amino acid present in foods, parenteral nutrition solutions, and food supplements), medicines that affect the central nervous system, medicines for treatment of depression: medicines of the SSRIs type (e.g., paroxetine, fluvoxamine), medicines of the SNRIs type (e.g., venlafaxine), monoamine oxidase inhibitors (MAOIs)-type medicines (e.g., moclobemide), linezolid, tricyclic antidepressants (e.g., nortriptyline, amitriptyline, imipramine, desipramine, clomipramine), pethidine, the *Hypericum* herb (St. John's Wort). These medicines increase the risk of side effects, including serotonin syndrome (see section 4 – Side effects).
- Anticoagulants (e.g., warfarin).
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as: aspirin that contains acetylsalicylic acid).

Inform the doctor of any additional medicine you are taking.

Use of the medicine and food:
The medicine can be taken without regard to meal times, namely, with or without food.

Use of the medicine and alcohol consumption:
Do not consume large amounts of alcohol when taking Duloxetine DR Teva®, since it may damage the liver.

Pregnancy and breastfeeding:
If you are pregnant or planning to become pregnant, consult a doctor before using this medicine. Use this medicine only after the doctor has decided that the benefit outweighs the risk. Make sure that the midwife and/or your doctor know you are taking Duloxetine DR Teva®. When similar medicines (SSRIs) are taken during pregnancy, they may increase the risk of a severe medical condition in infants called persistent pulmonary hypertension of the newborn (PPHN) that causes the baby to breathe faster and for his skin to be bluish. These symptoms usually appear in the first 24 hours after the baby is born. If this happens to your baby, refer to the baby's midwife and/or doctor immediately.
If you are using this medicine close to the due date, your baby may suffer side effects when he is born. The effects usually begin at birth or within a few days afterwards. These effects may include: floppy muscles, breathing, nervousness, not feeding properly, breathing problems and convulsions. If your baby has any of these side effects when he is born, or you are concerned about the baby's health, consult the midwife/doctor.
Tell the doctor if you are breastfeeding and consult him regarding use of this medicine. Use of this medicine while breastfeeding is not recommended.

Driving and use of machines:
Use of this medicine may impair alertness and therefore responsible caution is exercised when driving a car, when operating dangerous machinery and in any activity that requires alertness. It is preferable to abstain from these activities until the full effect of this medicine on you becomes apparent.

Important information about some of the ingredients of the medicine:
Regarding Duloxetine DR Teva® 30 mg:
Duloxetine DR Teva® 30 mg contains sugar (up to 101 mg sucrose).
Duloxetine DR Teva® 30 mg contains approximately 0.04 mg sodium.
Duloxetine DR Teva® 30 mg contains approximately 10.62 mg lactose monohydrate.
Regarding Duloxetine DR Teva® 60 mg:
Duloxetine DR Teva® 60 mg contains sugar (up to 202 mg sucrose).
Duloxetine DR Teva® 60 mg contains approximately 0.08 mg sodium.
Duloxetine DR Teva® 60 mg contains approximately 21.24 mg lactose monohydrate.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:
For treatment of depression or of neuropathic pain associated with peripheral diabetic neuropathy:
60 mg once a day. The doctor will prescribe the dose suitable for you.
For treatment of generalized anxiety:
The initial dosage is 30 mg once a day and after a certain amount of time, most patients will receive 60 mg once a day, but the doctor will prescribe the dose suitable for you. Based on your reaction to the medicine, the dose can be changed up to 120 mg per day.
Do not exceed the recommended dose.
Swallow the medicine whole with a little drink. Do not chew or crush the contents of the capsule.
If you accidentally took a higher dosage, call your doctor or pharmacist immediately. The symptoms of overdose can include sleepiness, coma, serotonin syndrome (a rare reaction), see section 4 – Side effects, convulsions, vomiting and rapid heart rate. If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the container of the medicine with you. Do not induce vomiting without explicit instruction from the doctor!
If you forget to take this medicine at the required time, take a dose as soon as you remember. If it is already time for the next dose, skip the forgotten dose and take only one dose. Do not take two doses together to compensate for a forgotten dose! Do not take, on a certain day, a dose larger than the daily Duloxetine DR Teva® dose that has been prescribed for you.
Adhere to the treatment as recommended by the doctor.
The effect of the medicinal treatment with Duloxetine DR Teva® is usually evident after 2-4 weeks of treatment. If there has been no improvement in your condition after this time, update your doctor.
Even if there is an improvement in your health condition, do not discontinue treatment with this medicine without consulting the doctor or pharmacist. If the doctor thinks there is no longer need for you to continue taking the medicine, he may lower the dosage for at least two weeks before discontinuing taking the medicine. Inform the doctor immediately in patients who abruptly stopped using the medicine, such as: dizziness, tingling/pricking sensation or electric shock-like sensation (particularly in the head), sleep disturbances (vivid dreams, nightmares, inability to sleep), fatigue, sensitivity, nervousness/nervousness, feeling anxious, nausea or vomiting, tremor, headaches, muscle pain, feeling irritable or diarrhea, excessive sweating or vertigo. These symptoms are not serious and usually disappear after a few days. If you feel that the side effects bother you, consult the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of this medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Duloxetine DR Teva® may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. These effects are mild to moderate and usually disappear after a few weeks.

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

Common (may affect more than 1 in 10 patients):
- Headache, sleepiness
- Nausea
- Dry mouth

Occur frequently (may affect up to 1 in 10 patients):
- Lack of appetite
- Difficulty falling asleep, nervousness, reduced sex drive, dental, difficulty or failure to experience orgasm, unusual dreams
- Dizziness, feeling sluggish, tremor, numb feeling, tingling/pricking sensation in the skin
- Blurred vision, ringing in the ears
- Strong heartbeats
- Hypertension, flushing and hot flashes
- Yawning
- Constipation, diarrhea, stomach pain, vomiting, heartburn or digestive system disorders
- Excessive sweating, rash
- Muscle pain, muscle contraction
- Painful urination, frequent urination
- Problems getting an erection, changes in ejaculation
- Falls (particularly in elderly people), fatigue
- Weight loss. In children and adolescents under 18 years of age who took this medicine for depression, some weight loss occurred when they first started taking this medicine. This effect matched the weight of children and adolescents of their age and sex after 6 months of treatment.
- Wind

Occur infrequently (may affect up to 1 in 100 patients):
- Throat inflammation that causes a hoarse voice
- Suicidal thoughts, difficulty falling asleep, teeth grinding, feeling disoriented, lack of motivation
- Involuntary twitches of the muscles, feeling of restlessness or an inability to sit or stand still, feeling nervous, difficulty concentrating, changes in sense of taste, difficulty controlling movements, poor sleep quality
- Enlarged pupils, problems with vision
- Feeling of dizziness or vertigo, ear pain
- Fast or irregular heartbeats
- Fainting, dizziness, fainting or dizziness on standing up, cold fingers
- Discomfort in the throat (throat tightness), nose bleed
- Vomiting blood or black stools, inflammation of the stomach lining, difficulty swallowing
- Inflammation of the liver that may cause abdominal pain and yellowing of the skin and whites of the eyes – refer to a doctor immediately!
- Night sweats, hives, cold sweats, sensitivity to sunlight, increased tendency to bruise
- Muscle tightness, muscle twitching
- Difficulty or inability to pass urine, difficulty at the beginning of urination, need to pass urine during the night, need to pass more urine than normal, decreased urine flow
- Abnormal vaginal bleeding, abnormal period (heavy or light, painful, painful or prolonged bleeding), pain in the testicle or scrotum
- Chest pain, feeling cold, feeling thirsty, shivering feeling hot, abnormal gait
- Weight gain
- Increase in blood levels of: liver enzymes, potassium, creatine phosphokinase, sugar, cholesterol – refer to a doctor immediately!

Occur rarely (may affect up to 1 in 1,000 patients):
- Severe allergic reaction which causes difficulty in breathing or dizziness with swollen tongue or lips
- Increased thyroid activity which may cause fatigue or weight gain
- Dehydration, low levels of sodium in the blood (mostly in elderly people). These symptoms may include: dizziness, weakness, confusion, sleepiness that is unusual, nausea, vomiting, spasms, falls, headache, difficulties concentrating, memory problems or feeling unreal – refer to a doctor immediately! Inappropriate secretion of anti-diuretic hormone (SIADH)
- Suicidal thoughts, mimic, manic behaviors, aggression and anger
- Serotonin syndrome – a reaction which can cause changes in the mental state (nervousness, hallucinations, coma), autonomic instability (rapid pulse, unstable blood pressure), hyperthermia, excessive sweating, flushing, increased body temperature, hyperactive reflexes, incoordination, stiffness, muscle spasms, increased reflexes, lack of coordination and/or agitation/irritability
- Inflammation of the mouth, red blood in stools, black stools
- Liver failure, yellowing of the skin or whites of the eyes (jaundice) – refer to a doctor immediately!
- Severe allergic reaction which may cause swelling of the face or throat – refer to a doctor immediately!
- Contraction of the jaw muscle
- Abnormal urine color
- Menopausal symptoms, abnormal production of breast milk

Additional side effects that have been observed:
- Back pains, cold, inflammation in the upper respiratory tract, flu, cough, pain in the pharynx, sharp drop in blood pressure when switching from a lying to sitting position or from sitting to standing (mainly at the beginning of treatment or after increasing dosage).

If a side effect occurred, if one of the side effects mentioned in this leaflet worsens, or if a side effect not mentioned in this leaflet, consult the doctor immediately.

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine and any other medicine must be kept in a safe place out of the reach and sight of children, in order to avoid risk of poisoning.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- In any case of doubt, consult the pharmacist who dispensed the medicine to you.
- Store in a dry place, at a temperature below 25°C.
- Do not store different medicines in the same package.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Duloxetine DR Teva® 60 mg:
Sugar spheres (up to 166 mg sucrose), Gelatin, Talc extra fine, Hypromellose phthalate, Hypromellose 2910, Lactose monohydrate 10.62 mg, Titanium dioxide 19 mg), Talc, Povidone, Triethyl citrate, Hypromellose (Pharmacoat 603), Hypromellose (Pharmacoat 606), Titanium dioxide, Colloidal silicon dioxide, Sodium lauryl sulfate (0.08 mg sodium), Brilliant blue FCF – FD&C blue 1, FD&C green 3, D&C yellow 10, Imprinting ink black.
Duloxetine DR Teva® 30 mg:
Sugar spheres (up to 91 mg sucrose), Gelatin, Talc extra fine, Hypromellose phthalate, Hypromellose 2910, Lactose monohydrate 10.62 mg, Titanium dioxide (5.5 mg), Talc, Povidone, Triethyl citrate, Hypromellose (Pharmacoat 603), Hypromellose (Pharmacoat 606), Titanium dioxide, Colloidal silicon dioxide, Sodium lauryl sulfate (0.04 mg sodium), Brilliant blue FCF – FD&C blue 1, Imprinting ink black.

What the medicine looks like and the contents of the package:
The capsules contain granules of duloxetine hydrochloride with an enteric coating that protects them from the acidity of the gastric juices and prevents their disintegration in the stomach. The 60 mg capsule is light blue and white with the imprinting of "7544" and "TEVA", respectively.
The 30 mg capsule is light blue and white with the imprinting of "TEVA" and "7543", respectively.
The package of Duloxetine DR Teva® 30 mg and the package of Duloxetine DR Teva® 60 mg contain 30 capsules.

License holder and address: Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Duloxetine DR Teva® 30 mg:
151.59.33802.00/01/02
Duloxetine DR Teva® 60 mg:
151.60.33803.00/01/02

This Leaflet was checked and approved by the Ministry of Health in March 2014.

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