

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: Duloxetine Teva DR 30 & Duloxetine Teva DR 60 Dosage form & strength: Each gastro-resistant hard capsule contains duloxetine hydrochloride equivalent to 30 mg or 60 mg duloxetine respectively
Response to 2nd Clinical Recommendation letter dated: 30.11.2020	Submitted to SAHPRA: 11/12/2020 - Sequence 0002

CLEAN FINAL PROPOSED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S5

DULOXETINE TEVA DR 30 (30 mg), gastro-resistant hard capsules

DULOXETINE TEVA DR 60 (60 mg), gastro-resistant hard capsules

Duloxetine hydrochloride

Contains sugar: each 30 mg capsule contains 101 mg sucrose and

each 60 mg capsule contains 201 mg sucrose.

Read all of this leaflet carefully before you start taking DULOXETINE TEVA DR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **DULOXETINE TEVA DR** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. WHAT DULOXETINE TEVA DR IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DULOXETINE TEVA DR

3. HOW TO TAKE DULOXETINE TEVA DR

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE DULOXETINE TEVA DR

1.3.2 Patient Information Leaflet

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Amendments have been effected according to SAHPRA recommendations, and the PIL is free of typographical and grammatical errors.

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Avisha Gordhan (B.Pharm)*



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6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT DULOXETINE TEVA DR IS AND WHAT IT IS USED FOR:

DULOXETINE TEVA DR contains the active substance duloxetine. **DULOXETINE TEVA DR** increases the levels of serotonin and noradrenaline in the nervous system.

DULOXETINE TEVA DR is used in adults to treat:

- depression
- diabetic neuropathic pain (often described as burning, stabbing, stinging, shooting or aching or like an electric shock. There may be loss of feeling in the affected area, or sensations such as touch, heat, cold or pressure may cause pain).

DULOXETINE TEVA DR starts to work in most people with depression or anxiety within two weeks of starting treatment, but it may take 2-4 weeks before you feel better. Tell your doctor if you do not start to feel better after this time. Your doctor may continue to give you **DULOXETINE TEVA DR** when you are feeling better to prevent your depression from returning.

In people with diabetic neuropathic pain it can take some weeks before you feel better. Talk to your doctor if you do not feel better after 2 months.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DULOXETINE TEVA DR:

Do not take DULOXETINE TEVA DR:

- if you are hypersensitive to duloxetine or to any of the other ingredients of this medicine (listed in section 6)
- if you have severe liver disease

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- if you have severe kidney disease
- if you are taking or have taken within the last 14 days, another medicine known as a monoamine oxidase inhibitor (MAOI) (see **Other medicines and DULOXETINE TEVA DR**)
- if you are pregnant or breastfeeding your baby.

Talk to your doctor if you have high blood pressure or heart disease. Your doctor will tell you if you should be taking **DULOXETINE TEVA DR**.


Warnings and precautions:

Take special care with **DULOXETINE TEVA DR**:

Talk to your doctor before taking **DULOXETINE TEVA DR** if you:

- have had seizures (fits)
- have had mania
- suffer from bipolar disorder
- have eye problems, such as certain kinds of glaucoma (increased pressure in the eye)
- suffer from certain heart disorders (ischaemic heart disease, for example angina pectoris)
- have kidney disease
- are taking other medicines to treat depression (see **Other medicines and DULOXETINE TEVA DR**)
- are taking St. John's Wort, a herbal treatment (*Hypericum perforatum*)
- have a history of bleeding disorders (tendency to develop bruises)
- are at risk of low sodium levels (for example if you are taking diuretics, especially if you are elderly)
- are currently being treated with another medicine which may cause liver damage

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- are taking other medicines containing duloxetine (see **Other medicines and DULOXETINE TEVA DR**)
- are taking other medicines known as MAOIs (Monoamine Oxidase Inhibitors) since you will need to stop taking the MAOI for at least 14 days before you start taking **DULOXETINE TEVA DR**, or wait at least 5 days after stopping **DULOXETINE TEVA DR**, before starting a MAOI (see **Other medicines and DULOXETINE TEVA DR**).

DULOXETINE TEVA DR may cause a sensation of restlessness or an inability to sit or stand still. You should tell your doctor if this happens to you.

DULOXETINE TEVA DR (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see **section 4**). In some cases, these symptoms have continued after stopping treatment.

Thoughts of suicide and worsening of your depression or anxiety disorder:

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this if you:

- have previously had thoughts about killing or harming yourself
- are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant

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If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents:

DULOXETINE TEVA DR is not for use in children under 18 years of age.

Other medicines and DULOXETINE TEVA DR:

Always tell your healthcare provider if you are taking any other medicine.


(This includes all complementary or traditional medicines.)

Especially talk to your doctor if you are taking one of the following:

The main ingredient of **DULOXETINE TEVA DR**, duloxetine, is used in other medicines for other conditions:

- anxiety and urinary incontinence.

Using more than one of these medicines at the same time should be avoided. Check with your doctor if you are already taking other medicines containing duloxetine.

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Your doctor should decide whether you can take **DULOXETINE TEVA DR** with other medicines. Do not start or stop taking any medicines, including those bought without a prescription and herbal remedies, before checking with your doctor.


You should also tell your doctor if you are taking any of the following:

Monoamine oxidase inhibitors (MAOIs): You should not take **DULOXETINE TEVA DR** if you are taking or have recently taken (within the last 14 days) another antidepressant medicine called a monoamine oxidase inhibitor (MAOI). Examples of MAOIs include moclobemide (an antidepressant) and linezolid (an antibiotic). Taking a MAOI together with many prescription medicines, including **DULOXETINE TEVA DR** 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 take **DULOXETINE TEVA DR**. Also, you need to wait at least 5 days after you stop taking **DULOXETINE TEVA DR** before you take a MAOI.

Medicines that cause sleepiness: These include medicines prescribed by your doctor including benzodiazepines, strong painkillers, antipsychotics, phenobarbitone and antihistamines.

Medicines that increase the level of serotonin: Triptans, tramadol, tryptophan, SSRIs (such as paroxetine and fluoxetine), SNRIs (such as venlafaxine), tricyclic antidepressants (such as clomipramine, amitriptyline), pethidine, St John's Wort and MAOIs (such as moclobemide and linezolid). These medicines increase the risk of side effects; if you get any unusual symptom while taking any of these medicines together with **DULOXETINE TEVA DR**, you should see your doctor.

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Oral anticoagulants or antiplatelet medicines: Medicines which thin the blood or prevent the blood from clotting. These medicines might increase the risk of bleeding.

Quinolone antibiotics: Medicines used to treat infections such as ciprofloxacin, lomefloxacin, norfloxacin, floxacin, moxifloxacin and levofloxacin. Your **DULOXETINE TEVA DR** dose may need to be reduced with these medicines.

DULOXETINE TEVA DR with food, drink and alcohol:

DULOXETINE TEVA DR may be taken with or without food, but it must be taken in the morning. Care should be taken if you drink alcohol while you are being treated with **DULOXETINE TEVA DR**.


Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before taking **DULOXETINE TEVA DR**.

Do not take **DULOXETINE TEVA DR** during pregnancy or when breastfeeding your baby.

Driving and using machines:

DULOXETINE TEVA DR may make you feel sleepy or dizzy. Do not drive or use any tools or machines until you know how **DULOXETINE TEVA DR** affects you.

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It is not always possible to predict to what extent **DULOXETINE TEVA DR** may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which **DULOXETINE TEVA DR** affects you.

DULOXETINE TEVA DR contains sucrose:

DULOXETINE TEVA DR contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **DULOXETINE TEVA DR**.

3. HOW TO TAKE DULOXETINE TEVA DR:

Do not share medicines prescribed for you with any other person.


Always take **DULOXETINE TEVA DR** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

DULOXETINE TEVA DR is for oral use. You should swallow your capsule whole with a drink of water.

The usual starting dose for **DULOXETINE TEVA DR** is one 60 mg capsule once a day, but your doctor will prescribe the dose that is right for you.

Children:

There is no experience with **DULOXETINE TEVA DR** in children under the age of 18 years, therefore its use is not recommended for children.

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Your doctor will tell you how long your treatment with **DULOXETINE TEVA DR** will last. If you have the impression that the effect of **DULOXETINE TEVA DR** is too strong or too weak, tell your doctor or pharmacist.

If you take more DULOXETINE TEVA DR than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdose include sleepiness, coma, serotonin syndrome (a rare reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles), fits, vomiting and fast heart rate. You may also experience shaking (tremor), loss of co-ordination and decreased appetite.

If you forget to take DULOXETINE TEVA DR:


Do not take a double dose to make up for forgotten individual doses.

If you stop taking DULOXETINE TEVA DR:

DO NOT stop taking your capsules without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need **DULOXETINE TEVA DR** he or she will ask you to reduce your dose over at least 2 weeks before stopping treatment altogether.

Some patients who stop taking **DULOXETINE TEVA DR** suddenly have had symptoms such as:

- dizziness, tingling feelings like pins and needles or electric shock-like feelings (particularly in the head), sleep disturbances (vivid dreams, nightmares, inability to sleep), fatigue, sleepiness, feeling

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restless or agitated, feeling anxious, feeling sick (nausea) or being sick (vomiting), shaking (tremor), headaches, muscle pain, feeling irritable, diarrhoea, excessive sweating or vertigo.

These symptoms are usually not serious and disappear within a few days, but if you have symptoms that are troublesome you should ask your doctor for advice.

4. POSSIBLE SIDE EFFECTS:

DULOXETINE TEVA DR can have side effects

Not all side-effects reported for **DULOXETINE TEVA DR** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **DULOXETINE TEVA DR**, please consult your healthcare provider for advice.

If any of the following happens, stop taking / using **DULOXETINE TEVA DR** and tell your doctor immediately or go to the casualty department at your nearest hospital:


- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **DULOXETINE TEVA DR**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent:

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- fast and/or irregular heartbeat
- increase in certain liver enzymes, inflammation of the liver, yellow coloring of skin and eyes (jaundice)
- Stevens-Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals), serious allergic reaction which causes swelling of the face or throat (angioedema)

These are all serious side effects. You may need urgent medical attention.


Tell your doctor if you notice any of the following:

Frequent side effects:

- lack of appetite
- trouble sleeping, feeling agitated, less sex drive, anxiety, difficulty or failure to experience orgasm, unusual dreams
- headache, feeling sleepy, sluggish, tremor, numbness, including numbness, pricking or tingling of the skin
- blurred eyesight
- tinnitus (hearing sound in the ear when there is no external sound)
- feeling the heart pumping in the chest
- increased blood pressure, flushing
- yawning
- nausea, vomiting, diarrhoea, or constipation
- indigestion, stomach pain and breaking wind
- increased sweating, (itchy) rash
- muscle pain, muscle spasm
- painful urination, frequent urination

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- problems getting an erection, changes in ejaculation
- falls (mostly in elderly people), tiredness
- weight loss

Less frequent side effects:

- throat inflammation that causes a hoarse voice
- decreased thyroid gland activity which can cause tiredness or weight gain
- dehydration, low levels of sodium in the blood (mostly in elderly people; the symptoms may include feeling dizzy, weak, confused, sleepy or very tired, or feeling or being sick, more serious symptoms are fainting, fits or falls), syndrome of inappropriate secretion of anti-diuretic hormone (SIADH)
- suicidal thoughts or behaviour, mania, grinding of teeth, (over activity, racing thoughts and decreased need for sleep), hallucinations, aggression and anger
- sudden involuntary jerks or twitches of the muscles, sensation of restlessness or an inability to sit or stand still, feeling nervous, difficulty concentrating, changes in sense of taste, difficulty controlling movement e.g. lack of co-ordination or involuntary movements of the muscles, restless legs syndrome, poor sleep quality
- “Serotonin syndrome” (a rare reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles), fits
- large pupils (the dark centre of the eye), problems with eyesight, increased pressure in the eye (glaucoma)
- feeling of dizziness or spinning (vertigo), ear pain
- dizziness, lightheadedness or fainting on standing up, cold fingers and/or toes
- vomiting blood, or black tarry stools (faeces), gastroenteritis, burping, difficulty swallowing

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- inflammation of the mouth, passing bright red blood in your stools, bad breath, inflammation of the large intestine (leading to diarrhoea)
- night sweats, hives, cold sweats, sensitivity to sunlight, increased tendency to bruise
- inflammation of the blood vessels in the skin (cutaneous vasculitis)
- muscle tightness, muscle twitching, contraction of the jaw muscle
- difficulty or inability to pass urine, difficulty to start urinating, needing to pass urine during the night, needing to pass more urine than normal, having a decreased urine flow
- abnormal vaginal bleeding, abnormal periods, including heavy, painful, irregular or prolonged periods, unusually light or missed periods, pain in the testicles or scrotum
- menopausal symptoms, abnormal production of breast milk in men or women
- chest pain, feeling cold, thirst, shivering, feeling hot, abnormal gait
- weight gain
- **DULOXETINE TEVA DR** may cause effects that you may not be aware of, such as increases in liver enzymes or blood levels of potassium, creatine phosphokinase, sugar, or cholesterol

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=ZA>

By reporting side effects, you can help provide more information on the safety of **DULOXETINE TEVA DR**.

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5. HOW TO STORE DULOXETINE TEVA DR:

Store all medicine out of reach of children.

Store at or below 25 °C.

Keep the capsules in the original container until required for use.

Do not use the capsules after the expiry date shown on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What DULOXETINE TEVA DR contains:

The active ingredient is duloxetine.

The other ingredients are:

Capsule content: sugar spheres, hypromellose phthalate, hypromellose, triethyl citrate, hydroxypropyl cellulose, talc.

Capsule shell 30 mg: black iron oxide (E172), Brilliant Blue FCF (E133), hypromellose (E464), titanium dioxide (E171), printing ink.

Capsule shell 60 mg: black iron oxide (E172), hypromellose (E464), titanium dioxide (E171), printing ink.

Printing ink: black iron oxide (E172), potassium hydroxide, propylene glycol, shellac, strong ammonia solution.

What DULOXETINE TEVA DR looks like and contents of the pack:

DULOXETINE TEVA DR 30: Hard capsules, size 2 with grey opaque body and blue opaque cap.

Marking DLX 30.

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DULOXETINE TEVA DR 60: Hard capsules, size 1EL with grey opaque body and white opaque cap. Marking DLX 60.

DULOXETINE TEVA DR is packed in:

HDPE containers with twist-off PP cap with integrated silica gel desiccant:

- 100 capsules.

OPA/Al/PVC-Al blister:

- 30 mg: 7, 14, 28, 30, 56, 98 and 100 capsules.

- 60 mg: 14, 28, 30, 56, 98 and 100 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd.

Maxwell Office Park,

Magwa Crescent West,

Waterfall City, Midrand,


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Registration Number:

Duloxetine Teva DR 30: 55/1.2/0307

Duloxetine Teva DR 60: 55/1.2/0308

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