

**Patient Information Leaflet DULOXETINE XR 30 & 60 BIOTECH**

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S5**

**DULOXETINE XR 30 BIOTECH hard gastro-resistant capsules**

**DULOXETINE XR 60 BIOTECH hard gastro-resistant capsules**

**Duloxetine (as hydrochloride)**

**Contains sugar (sucrose)**

DULOXETINE XR 30 BIOTECH: Each capsule contains 51,5 mg sucrose.

DULOXETINE XR 60 BIOTECH: Each capsule contains 103,0 mg sucrose.

**Read all of this leaflet carefully before you start taking DULOXETINE XR BIOTECH:**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DULOXETINE XR BIOTECH 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 XR BIOTECH is and what it is used for
2. What you need to know before you take DULOXETINE XR BIOTECH
3. How to take DULOXETINE XR BIOTECH
4. Possible side effects

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5. How to store DULOXETINE XR BIOTECH
  6. Contents of the pack and other information

## 1. What DULOXETINE XR BIOTECH is and what it is used for

DULOXETINE XR BIOTECH contains the active substance duloxetine. DULOXETINE XR BIOTECH increases the levels of serotonin and noradrenaline (norepinephrine) in the nervous system.

DULOXETINE XR BIOTECH 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).

## 2. What you need to know before you take DULOXETINE XR BIOTECH

**Do not take DULOXETINE XR BIOTECH if you:**

- Are hypersensitive (allergic) to duloxetine hydrochloride or any of the other ingredients of DULOXETINE XR BIOTECH (listed in section 6 of this leaflet).
- Are pregnant or breastfeeding (see section “Pregnancy and breastfeeding”).
- Have severe liver disease.
- Have severe kidney disease.
- Are taking or have taken within the last 14 days, another medicine known as a monoamine oxidase inhibitor (MAOI) (see “Other medicines and DULOXETINE XR BIOTECH”).

DULOXETINE XR BIOTECH should not be used in children under 18 years of age as safety has not been established.

### Warnings and precautions:

Tell your doctor before taking DULOXETINE XR BIOTECH if you:

- Have had seizures (fits).

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- Have had mania or suffer from bipolar disorder.
  - Have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
  - Suffer from hypertension or cardiac disease. Your doctor will tell you how to take DULOXETINE XR BIOTECH. Your doctor may also recommend you to monitor your blood pressure more frequently, while taking DULOXETINE XR BIOTECH.
  - Have liver or kidney disease (see section “Do not take DULOXETINE XR BIOTECH if you”).
  - Are taking St John’s wort (*Hypericum perforatum*), a herbal medicine used to treat depression (see “Other medicines and DULOXETINE XR BIOTECH”).
  - Are taking other medicines also containing duloxetine, which is the same active substance as contained in DULOXETINE XR BIOTECH (see “Other medicines and DULOXETINE XR BIOTECH”).
  - 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 other medicines which may cause liver damage, or if you use alcohol in substantial amounts.
  - Experience a sensation of restlessness or an inability to sit or stand still.
  - Are an elderly patient.
  - Are a smoker.

*Thoughts of suicide and worsening of your depression:*

If you are depressed, 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.

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 and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

*DULOXETINE XR BIOTECH may cause a condition called serotonin syndrome:*

This is a serious reaction which may cause, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles (see section 4). If this happens to you, speak to your doctor immediately. Also see section "Other medicines and DULOXETINE XR BIOTECH".

*DULOXETINE XR BIOTECH may cause symptoms of sexual dysfunction:*

See section 4. In some cases, these symptoms have continued after stopping treatment with DULOXETINE XR BIOTECH.

### **Children and adolescents:**

DULOXETINE XR BIOTECH should not be given to children and adolescents under the age of 18 years (see Do not take DULOXETINE XR BIOTECH). Patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) or self-harm when they take this class of medicines.

### **Other medicines and DULOXETINE XR BIOTECH:**

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not take DULOXETINE XR BIOTECH together with:

- Monoamine oxidase inhibitors (MAOIs) (see section “Do not take DULOXETINE XR BIOTECH if you”). Examples of MAOIs include moclobemide (an antidepressant) and linezolid (an antibiotic). Taking a MAOI together with DULOXETINE XR BIOTECH, can cause a serious or even life-threatening reaction called serotonin syndrome (see section “Warnings and precautions”).

You must wait at least 14 days after you have stopped taking an MAOI before you can take DULOXETINE XR BIOTECH. Also, you need to wait at least 5 days after you stop taking DULOXETINE XR BIOTECH before you take a MAOI.

- Fluvoxamine which is usually used to treat depression.
- Ciprofloxacin or enoxacin which are used to treat some infections.

Tell your doctor if you are using:

- Other medicines also containing duloxetine (see section “Warnings and precautions”).
- Medicines that cause sleepiness or can have an effect on your central nervous system. These include medicines prescribed by your doctor including benzodiazepines, strong painkillers, antipsychotics, phenobarbital (phenobarbitone), and antihistamines or alcohol.
- 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, nortriptyline and imipramine), pethidine, St John’s wort. These medicines increase the risk of serotonin syndrome (see sections “Warning and precautions”).
- Medicines that are metabolised by an enzyme called CYP2D6, such as risperidone (used to treat mental disorders), metoprolol (used to treat high blood pressure), flecainide and propafenone (used to treat abnormal fast heart rates).
- Oral anticoagulants or antiplatelet medicine (used to thin the blood or prevent the blood from clotting), such as warfarin or aspirin. These medicines might increase the risk of bleeding.

**DULOXETINE XR BIOTECH with food and alcohol:**

There are no known interactions between DULOXETINE XR BIOTECH and food. Care should be taken if you drink alcohol while you are being treated with DULOXETINE XR BIOTECH (see section “Other medicines and DULOXETINE XR BIOTECH”).

**Pregnancy and breastfeeding:**

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 health care provider for advice before taking DULOXETINE XR BIOTECH.

You should not take DULOXETINE XR BIOTECH if you are pregnant or breastfeeding (see section “Do not take DULOXETINE XR BIOTECH if you”).

**Driving and using machines:**

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

**DULOXETINE XR BIOTECH contains sucrose:**

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

**3. How to take DULOXETINE XR BIOTECH**

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

Always take DULOXETINE XR BIOTECH exactly as your doctor has told you. Check with your doctor if you are not sure.

The usual dose of DULOXETINE XR BIOTECH is 60 mg once a day, with or without food.

You should swallow your capsule whole with a drink of water.

Your doctor may change your dose if you suffer from certain renal or liver diseases.

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

**If you take more DULOXETINE XR BIOTECH than you should:**

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and your remaining tablets with you so the doctor can see what you have taken.

Symptoms of overdose include sleepiness, coma, serotonin syndrome (a 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.

**If you forget to take DULOXETINE XR BIOTECH:**

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual. Do not take a double dose to make up for a forgotten dose.

**If you stop taking DULOXETINE XR BIOTECH:**

Do not stop taking DULOXETINE XR BIOTECH without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need DULOXETINE XR BIOTECH your doctor will ask you to reduce your dose over at least 2 weeks before stopping treatment altogether.

Some patients who stop taking DULOXETINE XR BIOTECH 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 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 XR BIOTECH can have side effects.

Not all side effects reported for DULOXETINE XR BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DULOXETINE XR BIOTECH, please consult your health care provider for advice.

If any of the following happens, stop taking DULOXETINE XR BIOTECH 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 XR BIOTECH. 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:

- Suicidal thoughts, suicidal behaviour, mania (overactivity, racing thoughts and decreased need for sleep) and hallucinations (seeing or hearing things that are not real) (see section “Warnings and precautions”).
- Fast or irregular heartbeat.
- Weakening of the heart muscle (called broken heart syndrome), causing shortness of breath, heart pain, low blood pressure and fainting.

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- Serotonin syndrome (a rare reaction which may cause drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles) (see section “Warnings and precautions”).
  - Seizures (fits).
  - A sudden, dangerous rise in blood pressure and symptoms such as dizziness, headache.
  - Coughing, wheezing and shortness of breath which may be accompanied by a high temperature.
  - Vomiting blood, or black tarry stools (faeces), passing bright red blood in your stools.
  - Inflammation of the liver that may cause abdominal pain and yellowing of the skin or whites of the eyes, liver failure.
  - Stevens-Johnson syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals).
  - Inflammation of the blood vessels in the skin (cutaneous vasculitis).
  - 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 or excessive vaginal bleeding.

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, feeling anxious, less sex drive and difficulty or failure to experience orgasm (see section “Warnings and precautions”), unusual dreams.
- Dizziness, headache, feeling sluggish, tremor, numbness, pricking or tingling of the skin.
- Blurred eyesight.
- Tinnitus (ringing or buzzing noise in one or both ears).
- Increase in blood pressure.
- Flushing.

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- Yawning.
  - Constipation, diarrhoea, stomach pain, being sick (vomiting), heartburn or indigestion, breaking wind.
  - Increased sweating, (itchy) rash.
  - Muscle pain, muscle spasm.
  - Painful urination, frequent urination.
  - Problems getting an erection, changes in ejaculation (see section “Warnings and precautions”).
  - Falls, fatigue.
  - 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 (symptoms may include feeling dizzy or off-balance, weak, confused, sleepy or very tired).
- High blood sugar levels, characterised by symptoms such as increased thirst, headaches, blurred vision, trouble concentrating, fatigue.
- Syndrome of inappropriate antidiuretic hormone secretion (SIADH), a condition in which the body makes too much antidiuretic hormone (ADH). SIADH causes the body to retain too much water.
- Aggression and anger.
- Difficulty sleeping, grinding or clenching the teeth, feeling disorientated, lack of motivation.
- 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 coordination or involuntary movements of the muscles, restless legs syndrome, poor sleep quality.
- Large pupils (the dark centre of the eye), problems with eyesight.
- Increased pressure in the eye (glaucoma).

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- Feeling of dizziness or spinning sensation of the head (vertigo), ear pain.
  - Fainting, dizziness, light-headedness or fainting on standing up, cold fingers or toes.
  - Throat tightness, nose bleeds.
  - Bad breath, inflammation of the large intestine (leading to diarrhoea), burping, difficulty swallowing.
  - Night sweats, hives, cold sweats, sensitivity to sunlight, increased tendency to bruise.
  - Muscle tightness, muscle twitching.
  - Contraction of jaw muscles.
  - Abnormal urine odour.
  - Abnormal menstrual periods, including heavy, painful, irregular or prolonged periods, unusually light or missed periods, pain in the testicles or scrotum.
  - Menopausal symptoms (hot flushes, night sweats, sleep problems, mood changes).
  - Abnormal production of breast milk in men or women.
  - Chest pain, feeling cold, thirst, shivering, feeling hot.
  - Weight gain.
  - DULOXETINE XR BIOTECH may cause effects that you may not be aware of, such as increases in liver enzymes or blood levels of potassium, 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 or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of DULOXETINE XR BIOTECH.

### **5. How to store DULOXETINE XR BIOTECH**

- Store at or below 25 °C.

- Protect from moisture.
- Keep blister strips in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What DULOXETINE XR BIOTECH contains:

The active ingredient is duloxetine.

Each capsule contains 30 or 60 mg duloxetine (as hydrochloride).

The other ingredients are: Sugar spheres, hypromellose, talc, sucrose, hypromellose phthalate, triethyl citrate, gelatine, FD&C Blue 2 (E132), titanium dioxide (E171), yellow iron oxide (E172), shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonium solution, purified water, potassium hydroxide (only in DULOXETINE XR 60 BIOTECH).

### What DULOXETINE XR BIOTECH looks like and contents of the pack:

DULOXETINE XR 30 BIOTECH: Opaque blue/opaque white, size 3, hard gelatine capsule, with “157” printed on the body and “A” on the cap with green ink, filled with white to off-white pellets.

DULOXETINE XR 60 BIOTECH: Opaque blue/opaque green, size 1, hard gelatine capsule, with “158” printed on the body and “A” on the cap with white ink, filled with white to off-white pellets.

DULOXETINE XR BIOTECH is packed in:

- Silver aluminium/aluminium blister strips, or
- Silver aluminium/clear transparent PVC/Aclar blister strips.

Pack sizes: 28, 30 or 80 capsules.

Not all pack sizes may be marketed.

**Holder of certificate of registration:**

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