Patient Information Leaflet

SCHEDULING STATUS

S5

DUZELA 30 mg hard gastro-resistant capsules

DUZELA 60 mg hard gastro-resistant capsules

Duloxetine (as hydrochloride)

Contains sugar (sucrose and mannitol)

Duzela 30: Each capsule contains 64,2 mg sucrose and 6,7 mg mannitol.

Duzela 60: Each capsule contains 128,4 mg sucrose and 13,4 mg mannitol.

Read all of this leaflet carefully before you start taking DUZELA:

- 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.
- DUZELA 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 DUZELA is and what it is used for

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

DUZELA 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).

DUZELA starts to work in most people with depression 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 DUZELA when you are feeling better to prevent your depression from returning.

2. What you need to know before you take DUZELA

Do not take DUZELA if you:

- Are hypersensitive (allergic) to duloxetine hydrochloride or any of the other ingredients of DUZELA (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 DUZELA”).
- Are younger than 18 years of age.
- Have uncontrolled (i.e. not responding to treatment) narrow-angle glaucoma (a condition that causes increased pressure in the eye) or uncontrolled high blood pressure.

Warnings and precautions:

Tell your doctor before taking DUZELA if you:

- Have had seizures (fits).
- 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 DUZELA. Your doctor may also recommend you to monitor your blood pressure more frequently, while taking DUZELA.
- Have liver or kidney disease (see section “Do not take DUZELA if you”).
- Are taking St John’s wort (*Hypericum perforatum*), a herbal medicine used to treat depression (see “Other medicines and DUZELA”).
- Are taking other medicines also containing duloxetine, which is the same active substance as contained in DUZELA (see “Other medicines and DUZELA”).

- A history of bleeding disorders (tendency to develop bruises), especially if you are pregnant (see Pregnancy and breastfeeding).
- 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 or anxiety disorder:

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 or have an anxiety disorder 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.

DUZELA may cause a condition called serotonin syndrome or neuroleptic malignant syndrome:

This is a serious reaction which may cause, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles, fast heartbeat, confusion, increased muscle enzymes (determined by blood test) (see section 4). If this happens to you, speak to your doctor immediately. Also see section “Other medicines and DUZELA”.

DUZELA (also called selective serotonin reuptake inhibitors (SSRIS/serotonin norepinephrine reuptake inhibitors (SNRIs)) may cause symptoms of sexual dysfunction: See section 4. In some cases, these symptoms have continued after stopping treatment with DUZELA.

DUZELA may cause Takotsubo cardiomyopathy. Takotsubo cardiomyopathy (also known as stress cardiomyopathy) is a condition where your heart muscle becomes suddenly weakened, due to your body releasing stress hormones in your blood. This condition is reversible upon stopping DUZELA and receiving appropriate treatment. It is important for you that your doctor knows about all your medical conditions.

Children and adolescents:

DUZELA should not be given to children and adolescents under the age of 18 years.

Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take 2 this class of medicines. Despite this, your doctor may prescribe DUZELA for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed DUZELA for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking DUZELA. Also, the long-term safety effects concerning growth, maturation, and cognitive and behavioural development of DUZELA in this age group have not yet been demonstrated.

Other medicines and DUZELA:

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

Do not take DUZELA together with:

- Monoamine oxidase inhibitors (MAOIs) (see section “Do not take DUZELA if you”). Examples of MAOIs include moclobemide (an antidepressant) and linezolid (an antibiotic).Taking a MAOI together with DUZELA, 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 DUZELA. Also, you need to wait at least 5 days after you stop taking DUZELA before you take a MAOI.

- Fluvoxamine which is usually used to treat depression.

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 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 *(Hypericum perforatum)*. These medicines increase the risk of serotonin syndrome (see section “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), depipramine (used to treat depression).
- Oral anticoagulants or antiplatelet medicine (used to thin the blood or prevent the blood from clotting), such as Warfarin, NSAIDs or aspirin. These medicines might increase the risk of bleeding.

DUZELA with food and alcohol:

DUZELA may be taken with or without food. Care should be taken if you drink alcohol while you are being treated with DUZELA (see section “Other medicines and DUZELA”).

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

If you take DUZELA near the end of your pregnancy there is an increased risk of excessive vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking DUZELA so they can advise you.

Make sure your midwife and/or doctor knows you are on DUZELA. When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and 3 appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you take DUZELA near the end of your pregnancy, your baby might have some symptoms when it is born. These usually begin at birth or within a few days of your baby being born. These symptoms may include floppy muscles, trembling, jitteriness, not feeding properly, trouble with breathing and fits. If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, contact your doctor or midwife who will be able to advise you.

You should not take DUZELA if you are breastfeeding your baby.

Driving and using machines:

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

DUZELA contains sucrose:

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

DUZELA contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take DUZELA

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

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

The usual dose of DUZELA is 60 mg once a day, with or without food. DUZELA is for oral use.

You should swallow your capsule whole with a drink of water. Your doctor may change your dose if you suffer from certain renal or kidney diseases.

For depression and diabetic neuropathic pain:

The usual dose of DUZELA is 60 mg once a day. Your doctor may adjust the dose depending on how you respond to treatment. To help you remember to take DUZELA, you may find it easier to take it at the same times every day. Your doctor will tell you how long your treatment with DUZELA will last. If you have the impression that the effect of DUZELA is too strong or too weak, tell your doctor or pharmacist.

If you take more DUZELA than you should:

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

Symptoms of overdosage may include sleepiness, a state of prolonged unconsciousness (coma), seizures (fits), vomiting, a fast heart rate and serotonin syndrome (a rare reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles) (see section “Warnings and precautions”).

If you forget to take DUZELA:

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. Do not take more than the daily amount of DUZELA that has been prescribed for you in one day.

If you stop taking DUZELA:

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

Some patients who stop taking DUZELA 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

DUZELA can have side effects.

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

If any of the following happens, stop taking DUZELA 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 DUZELA. 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.
- Serotonin syndrome (a rare reaction which may cause feeling of great happiness, 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 (jaundice), 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, feeling tense, 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.
- Yawning.
- Constipation, dry mouth, 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 (mostly in elderly people), 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).
- 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, abnormal vaginal bleeding 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, feeling abnormal, general feeling of discomfort or uneasiness, abnormal gait.
- Weight gain.
- DUZELA 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, increases in bilirubin. Your doctor will advise you about the tests you may require.
- Abnormally high blood pressure or a severe increase in blood pressure that can lead to a stroke.
- Angioedema, marked by patches of confined swelling involving the skin, the layers beneath the skin, the mucous membranes and soft internal organs of the body

Unknown frequent side effects

- signs and symptoms of a condition called “stress cardiomyopathy” which may include chest pain, shortness of breath, dizziness, fainting, irregular heartbeat.

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 or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eRporting platform (who-

umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DUZELA.

Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email or telephonically: pharmacovigilance.africasme@sunpharma.com or tel:+27(0) 12 643 2000

5. How to store DUZELA

- Store at or below 25 °C.
- Keep in the original container in order to protect from light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the packaging.
- 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 DUZELA contains:

The active ingredient is duloxetine (as hydrochloride).

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

The other ingredients are: Sugar spheres, hypromellose, mannitol, purified talc, sucrose, methacrylic acid copolymer dispersion, triethyl citrate, sodium hydroxide, gelatine, sodium lauril sulfate, FD&C Blue 2 (E132), titanium dioxide (E171), yellow iron oxide (E172) (only in DUZELA 60), shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, potassium hydroxide, purified water black iron oxide (E172) (only in DUZELA 30)

What DUZELA looks like and contents of the pack:

DUZELA 30: Size 3 hard gelatine capsule, consisting of a blue cap and white body with “382” imprinted in black ink on the cap and body, containing white to off-white pellets.

DUZELA 60: Size 1 hard gelatine capsule, consisting of a blue cap and green body with “383” imprinted in white ink on the cap and body, containing white to off-white pellets.

DUZELA is packed in a white, round HDPE bottle with a child-resistant, white polypropylene cap

with liner.

Pack sizes: 30, 90 or 100 capsules

Not all pack sizes may be marketed.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

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1724

Tel: +27 (0) 12 643 2000

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11 March 2026

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DUZELA 30: 48/1.2/0680

DUZELA 60: 48/1.2/0681

Date of registration:

10 November 2020

Access to the corresponding PIL translation:
The PIL is available in one other language (Afrikaans), a copy is accessible on the company website: https://sunpharma.com/south-africa-products/