APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

YELATE 30, duloxetine hydrochloride equivalent to duloxetine 30 mg, capsules

YELATE 60, duloxetine hydrochloride equivalent to duloxetine 60 mg, capsules

Duloxetine hydrochloride

Contains sugar (sucrose).

Read all of this leaflet carefully before you start taking YELATE

- 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.
- YELATE 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 YELATE is and what it is used for
2. What you need to know before you take YELATE
3. How to take YELATE
4. Possible side effects
5. How to store YELATE
6. Contents of the pack and other information

1. What YELATE is and what it is used for

YELATE is used to treat depression in adults.

YELATE is also used to treat diabetic neuropathic pain in adults (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 YELATE

Do not take YELATE if you:

- are allergic (hypersensitive) to duloxetine or any of the other ingredients of YELATE. (See **"What YELATE contains"**).
- are younger than 18 years of age
- are pregnant or if you are breastfeeding your baby
- have severe liver disease
- have severe kidney disease
- are taking or have taken, within the last 14 days, a medicine known as a monoamine oxidase inhibitor (MAOI). (See **"Other medicines and YELATE"**).
- 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

Before taking YELATE, talk with your doctor:

-If you have 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 antidepressant medications, 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.

If you have thoughts of harming or killing yourself at any time, contact your doctor, pharmacist or other healthcare professional 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.

Also talk to your doctor before you take YELATE if you:

- are taking any other medicines and especially if you are taking or have taken other medicines to treat depression, including non-prescription medications. (See **"Other medicines and YELATE"**).
- YELATE may cause a serious condition called serotonin syndrome if taken with certain medicines that increase the level of serotonin. (See **"Other medicines and YELATE"**).
- are taking St. John's Wort (*Hypericum perforatum*), a herbal medicine
- have kidney, liver or heart disease
- have had mania (abnormally elated mental state)
- have had seizures (fits)
- have eye problems, such as certain kinds of glaucoma (increased pressure

in the eye)

- have diabetes
- suffer from bipolar disorder (mood swings)
- have a history of bleeding disorders or a tendency to develop bruises, especially if you are pregnant (see **"Pregnancy and breastfeeding"**)
- have high blood pressure. YELATE can increase your blood pressure. Your blood pressure should be checked prior to and regularly while you are taking YELATE.
- are at risk of low sodium levels (for example if you are taking diuretics (also known as water pills)), especially if you are elderly
- you drink large amounts of alcohol.

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

YELATE 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 YELATE and receiving appropriate treatment.

It is important for you that your doctor knows about all your medical conditions.

Other medicines and YELATE

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

(This includes all complementary or traditional medicines.)

YELATE may have increased adverse effects or may increase the adverse effects of other medicines when taken together, or the effectiveness of either may decrease.

If you are taking YELATE do not start or stop taking any medicines, including those bought without a prescription and herbal remedies, before checking with your doctor.

Talk to your doctor before taking YELATE with the following medicines:

- **Monoamine oxidase inhibitors (MAOIs):**

  You should not take YELATE if you are taking, or have recently taken another antidepressant medicine called a monoamine oxidase inhibitor (MAOI) (e.g. tranylcypromine and selegiline) or linezolid. (See **"Do not take YELATE"**).

  Taking a MAOI together with YELATE, can cause serious or even life-threatening side effects.

  You must wait at least 14 days after you have stopped taking linezolid or a MAOI before you can take YELATE. Also, you need to wait at least 5 days after you stop taking YELATE before you take a MAOI.
- **Medicines that increase the level of serotonin:** Triptans (such as zomitriptan and sumatriptan), tramadol, tryptophan, SSRIs (such as paroxetine and fluoxetine), SNRIs, tricyclic antidepressants (such as clomipramine, amitriptyline), pethidine, St John's Wort and MAOI's.

  These medicines increase the risk of side-effects; if you get any unusual symptom taking any of these medicines together with YELATE, you should see your doctor.
- **Medicines that cause sleepiness:** Tranquilisers and sedatives (such as benzodiazepines), strong painkillers, antipsychotics (such as risperidone, olanzapine and quetiapine), phenobarbital, antihistamines (such as chlorphenamine and promethazine)
- antibiotics known as quinolones such as ciprofloxacin, levofloxacin and moxifloxacin
- medicines for thinning the blood such as warfarin: Co-administration with YELATE may increase your risk of bleeding
- medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) including

aspirin, ibuprofen, naproxen, diclofenac and others. Taking any of these medicines with YELATE may cause you to bruise or bleed easily.

- antidepressant medicines (fluvoxamine, desipramine, paroxetine).

YELATE with food and drink

- YELATE can be taken with or without food.
- You should take care if you drink alcohol with YELATE. It may increase your risk of liver damage.

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 receiving this medicine.

You should not take YELATE if you are pregnant.

If you take YELATE 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 YELATE so they can advise you.

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

Driving and using machines

YELATE may make you feel sleepy or dizzy or less alert.

Do not drive or use any tools or machines until you know how YELATE affects you.

YELATE contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking YELATE. YELATE contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take YELATE

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

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

YELATE is for oral use.

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

Do not break, crush or chew the capsules.

It may take a few weeks before you see the full benefit of YELATE.

For depression and diabetic neuropathic pain:

The usual dose of YELATE 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 YELATE, you may find it easier to take it at the same time every day. Your doctor will tell you how long your treatment with YELATE will last. If you have the impression that the effect of YELATE is too strong or too weak, tell your doctor or pharmacist.

If you take more YELATE than you should

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

If you forget to take YELATE

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 YELATE that has been prescribed for you in one day.

If you stop taking YELATE

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 YELATE, he or she will ask you to reduce your dose over at least 2 weeks before stopping treatment altogether.
Some patients who stop taking YELATE suddenly have had symptoms such as:
Headache, feeling sick (nausea), being sick (vomiting), dizziness, inability to sleep, feeling anxious, fatigue, feeling irritable, nightmares, diarrhoea, excessive sweating, vertigo (a feeling of dizziness or "spinning") or tingling feelings like pins and needles or electric shock-like feelings.

4. Possible side effects

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

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

-If you have an allergic reaction to YELATE with effects such as swelling of the mouth, tongue or face and/or throat, difficulty to breathe or swallow, red lumpy skin rash (hives), dizziness (which may be as a result of a sudden fall in blood pressure leading to collapse or shock).
-If you experience itching, right upper-belly pain, dark urine, yellow skin/eyes (jaundice), and unexplained flu-like symptoms while taking YELATE.

These are signs of severe liver problems which can sometimes be fatal.

-If you start feeling agitated and disorientated, have a contracted jaw muscle, have convulsions (seizures or fits): These are signs of "**Serotonin syndrome**", a less

frequent reaction which may also cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles, vomiting and fast heart rate.

-if you develop severe skin blisters with redness around them, or a serious or peeling rash, hives and mouth sores: These are symptoms of **Stevens-Johnson syndrome**, a sometimes fatal form of allergic skin disease which also has severe flu-like early symptoms. This condition affects the mucous membranes, lungs, digestive tract, heart, and kidneys.

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

Contact your doctor, pharmacist or healthcare professional immediately:

- if you have thoughts about suicide or hurting yourself. (See **"Warnings and precautions"**).

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Contact your doctor as soon as possible:

- if you have any new or worsening symptoms such as mood or behaviour changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), or become more depressed, or have mood swings.

- if you experience the following symptoms: sensation of restlessness or an inability to sit or stand still. These can be symptoms of a condition known as akathisia.

- if you experience symptoms such as feeling dizzy, weak, confused, sleepy or very tired, or feeling or being sick, or more serious symptoms are fainting, fits or falls. These can be signs of dehydration and low levels of sodium in the blood as a result of taking YELATE.

Other side effects that may occur with YELATE include:

Frequent side effects

-Feeling the heart pumping in the chest

-Constipation, dry mouth, nausea, vomiting, diarrhoea, indigestion or heartburn, breaking wind, stomach discomfort, abdominal pain, vomiting blood or blood in stools

-Fatigue, lack or loss of strength and energy/weakness, shivering or trembling, falls

-Weight loss, increased blood pressure

-Decreased appetite

-Feeling dizzy, headache, drowsiness, feeling sluggish, sleepiness, sedation, trembling or quivering, numbness, including numbness, pricking or tickling of the skin

-Dizziness accompanied by a sensation of 'spinning'

- Unpleasant alteration of taste sensation, often with a metallic taste

-Sleeplessness, anxiety, feeling jittery, nervousness, restlessness, feeling tense, disrupted sleep patterns, feeling agitated, unusual dreams

-Reduced sex drive, difficulty or failure to experience orgasm

- Blurred eyesight

-Yawning

- Increased sweating

-Hot flushes, flushing

-Muscle pain, neck pain, muscle spasm

-Frequent urination.

Less frequent side effects

-Allergic reactions

-Fast and/or irregular heart beat

- Takotsubo cardiomyopathy (a condition affecting heart muscle)

-Abnormally high blood pressure or a severe increase in blood pressure that can lead

to a stroke

-Enlarged centre of the eye, problems with eye sight, increase in pressure in the eye (detection normally requires an eye test)

-Burping, infection of the digestive tract, inflammation of the mucous lining in the mouth, bad breath, inflammation of the stomach, difficulty swallowing, passing bright red blood in your stools

-Feeling abnormal, shivering, feeling hot, feeling cold, general feeling of discomfort or uneasiness, feeing thirsty, abnormal gait, chest pain

-Inflammation of the liver causing effects such as abdominal pain and yellowing of the skin or whites of the eyes.

-Liver failure with or without yellowing of the skin or whites of the eyes (jaundice)

-Increased weight

-YELATE may cause effects that you may not be aware of, such as an increase in liver enzymes, increase in blood levels of certain enzymes, increase in blood levels of potassium, increases in bilirubin, and of sugar and cholesterol. Your doctor will advise you about the tests you may require.

- Muscle feeling tight, muscle twitching, contraction of the jaw muscle

-Seizures (fits), difficulty concentrating, difficulty controlling movement e.g. lack of coordination or involuntary movements of the muscles, poor sleep quality, sudden involuntary jerks or twitches of the muscles, restless legs syndrome, movement disorders

-Grinding or clenching the teeth, feeling disorientated, lack of motivation, mania (over activity, racing thoughts and decreased need for sleep), hallucinations, aggression and anger

-Involuntary delay or inability to start urine flow, needing to pass urine during the night, painful urination, needing to pass more urine than normal, having a decreased urine

flow, abnormal urine odour

-Syndrome of inappropriate secretion of anti-diuretic hormone (SIADH)

- Problems getting an erection, changes in ejaculation, pain in the testicles, sexual dysfunction, abnormal production of breast milk in men or women, menopausal symptoms, abnormal vaginal bleeding, abnormal periods, including heavy, painful, irregular or prolonged periods, unusually light or missed periods

-Night sweats, sun sensitivity with redness of the skin similar to sunburn, skin outbreaks, hives, skin bruises, itching skin, cold sweats

-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

-Cold hands and feet, a fall in blood pressure that occurs on standing up after lying down causing dizziness and feeling faint, fainting

-Throat inflammation that causes a hoarse voice

- Decreased thyroid gland activity which can cause weight gain or tiredness

-Ear pain, tinnitus (hearing sound in the ear when there is no external sound)

-Throat tightness, nose bleeds.

- excessive vaginal bleeding shortly after birth (postpartum haemorrhage), see **"Pregnancy and breastfeeding"** in section 2 for more information

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 **"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

YELATE.

5. How to store YELATE

Store all medicines out of reach of children.

Store at or below 25 °C and protect from moisture.

Do not store in bathrooms.

Keep the capsules in the original blisters and keep the blisters in the carton until required for use.

Keep the capsules in the plastic container until required for use and keep the container tightly closed.

Do not use after the expiry date stated on the containers/labels.

Disposal of unused medicines

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

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What YELATE contains

YELATE 30: The active substance is duloxetine hydrochloride.

Each delayed-release capsule contains enteric coated pellets of duloxetine hydrochloride equivalent to duloxetine 30 mg.

Contains sugar (sucrose).

The other ingredients are: Glycine, hydroxypropyl methylcellulose, hypromellose phthalate, talc and triethyl citrate.

Capsule shell ingredients: FD&C blue 2, gelatin, sodium lauryl sulphate and titanium dioxide. Edible printing ink (golden yellow): Shellac, propylene glycol and yellow iron oxide (E172).

YELATE 60: The active substance is duloxetine hydrochloride.

Each delayed-release capsule contains enteric coated pellets of duloxetine hydrochloride equivalent to duloxetine 60 mg.

Contains sugar (sucrose).

The other ingredients are: Glycine, hydroxypropyl methylcellulose, hypromellose phthalate, talc and triethyl citrate.

Capsule shell ingredients: FD&C blue 2, gelatin, sodium lauryl sulphate and titanium dioxide. Edible printing ink (white): Shellac, potassium hydroxide, propylene glycol and titanium dioxide (E171).

What YELATE looks like and contents of the pack

YELATE 30: White to off white spherical enteric coated pellets filled in size '3' hard gelatin capsules with opaque blue coloured cap and opaque white coloured body, imprinted 'RDY609' on cap and '30mg' on body with golden yellow ink.

YELATE 60: White to off white spherical enteric coated pellets filled in size '1' hard gelatin capsules with opaque blue coloured cap and opaque green coloured body, imprinted 'RDY610' on cap and '60mg' on body with white ink.

HDPE containers: The capsules are packed in white HDPE containers with white plastic caps containing 30/60/90/100/500/1000 capsules.

Blister packs: The capsules are packed in Alu/Alu blisters of 7/10 capsules per blister strip.

Blisters strips (4 x 7 or 3 x 10 resulting in a pack of 28 or 30 capsules) are packed in plain white duplex cartons.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd

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YELATE 30: 44/1.2/0114

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Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website: http://www.drreddys.co.za

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

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