SCHEDULING STATUS

S5

DUELOKS 30 (Capsules)

Duloxetine hydrochloride equivalent to 30 mg of duloxetine.

Contains: sugar (sucrose 51.5 mg)

DUELOKS 60 (Capsules)

Duloxetine hydrochloride equivalent to 60 mg of duloxetine.

Contains sugar (sucrose 103 mg*)*

Read all of this leaflet carefully before you start taking DUELOKS

- 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
- **DUELOKS** has been prescribed for personally and you should not share your medicine with other people. It may them, even if their symptoms

What is in this leaflet

1. What DUELOKS is and what it is used for

2. What you need to know before you take DUELOKS

3. How to take DUELOKS

4. Possible side effects

5. How to store DUELOKS

6. Contents of the pack and other information

1. WHAT DUELOKS IS AND WHAT IT IS USED FOR:

DUELOKS contains the active substance duloxetine. **DUELOKS** increases the levels of serotonin and noradrenaline (norepinephrine) in the nervous system. **DUELOKS** is used in adults to treat depression, and 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).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE

Do not take DUELOKS:

- If you are hypersensitive or have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) to duloxetine hydrochloride, or any of the other ingredients in **DUELOKS.**
- If you are pregnant of breastfeeding
- If you have liver disease
- 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 'Taking other medicines')
- If you are taking other medicines containing duloxetine (see 'Other medicines and **DUELOKS**')
- If the patient is under 18 years of age as safety in children has not been established.

Warnings and precautions:

Tell your healthcare professional if you:

- are taking St. John's Wort, a herbal treatment (Hypericum perforatum)

- have liver or kidney disease
- 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 hypertension or cardiac disease
- 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 or if you use alcohol in substantial amounts
- are taking other medicines containing duloxetine (see 'Other medicines and **DUELOKS**')

DUELOKS may cause a sensation of restlessness or an inability to sit or stand still. Medicines like **DUELOKS** (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:

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. Tests have shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were previously 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.

Children and adolescents under 18 years of age

DUELOKS should normally not be used for children and adolescents under 18 years (see "Do not take **DUELOKS**). 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 **DUELOKS**.

Other medicines and DUELOKS:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

The use of **DUELOKS** with these medicines may cause undesirable interactions.

It is especially important to also tell your doctor if you are taking any of the following:

Monoamine oxidase inhibitors (MAOIs): You should not take **DUELOKS** if you are taking or have recently taken (within the last 14 days) another antidepressant medicine called a monoamine oxidase inhibitor (MAOI). Taking a MAOI together with many prescription medicines, including **DUELOKS**, 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 **DUELOKS.** Also, you need to wait at least 5 days after you stop taking **DUELOKS** 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), tricyclics (such as clomipramine, amitriptyline), pethidine, St John's Wort and venlafaxine. These medicines increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with **DUELOKS,** you should see your doctor.

Oral anticoagulants or antiplatelet medicines:

Medicines which thin the blood or prevent the blood from clotting e.g. warfarin, aspirin. These medicines might increase the risk of bleeding.

The main ingredient of **DUELOKS,** duloxetine, is used under different trademarks for other conditions. Using more than one of these medicines at the same time as **DUELOKS** should be avoided. Check with your doctor if you are already taking other medicines containing duloxetine.

DUELOKS with food and drink and alcohol:

DUELOKS may be taken with or without food. Care should be taken if you drink alcohol while you are being treated with **DUELOKS.**

Pregnancy and breastfeeding and fertility

You should not take **DUELOKS** if you are pregnant (see 'Do not take **DUELOKS**').

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 this medicine.

Duloxetine is excreted into breast milk. The use of **DUELOKS** while breastfeeding is contraindicated (see “Do not take **DUELOKS**.

Driving and using machines:

If you feel drowsy or dizzy while taking **DUELOKS** do not drive, use tools or use machinery

DUELOKS contains sucrose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **DUELOKS**.

3. HOW TO TAKE DUELOKS

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

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

For depression and diabetic neuropathic pain:

The usual dose of **DUELOKS** is 60 mg once a day, but your doctor will prescribe the dose that is right for you.

The tablets should be swallowed whole with a sufficient volume of water and may be taken with or without food.

If you take more DUELOKS 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.

If you forget to take DUELOKS

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

Take the missed dose 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 more than the daily amount of **DUELOKS** that has been prescribed for you in one day.

If you stop taking DUELOKS

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 **DUELOKS** he or she will ask you to reduce your dose over at least 2 weeks before stopping treatment altogether.

Some patients who stop taking **DUELOKS** 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

DUELOKS can have side effects.

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

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

- serious allergic reaction which causes difficulty in breathing or dizziness with swollen tongue or lips, allergic reactions
- suicidal behaviour, mania (over activity, racing thoughts and decreased need for sleep), hallucinations, aggression and anger
- 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 very serious side effects. If you have them, you may have had a serious reaction to DUELOKS . 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:

- throat inflammation that causes a hoarse voice
- suicidal thoughts, 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
- feeling of dizziness or “spinning” (vertigo), ear pain
- fast and/or irregular heartbeat
- fainting, dizziness, light-headedness or fainting on standing up, cold fingers and/or toes
- throat tightness, nose bleeds
- vomiting blood, or black tarry stools (faeces), gastroenteritis, burping, difficulty swallowing
- inflammation of the liver that may cause abdominal pain and yellowing of the skin or whites of the eyes
- night sweats, hives, cold sweats, sensitivity to sunlight, increased tendency to bruise
- muscle tightness, muscle twitching
- 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
- chest pain, feeling cold, thirst, shivering, feeling hot, abnormal gait
- weight gain

• **DUELOKS** 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

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

Tell your doctor if you notice any of the following:

Frequent:

- headache, feeling sleepy
- feeling sick (nausea), dry mouth
- trouble sleeping, feeling agitated, less sex drive, anxiety, difficulty or failure to experience orgasm, unusual dreams
- dizziness, feeling 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
- increased 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
- falls (mostly in elderly people), fatigue

- weight loss

Less frequent:

- 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)
- “Serotonin syndrome” (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles), fits
- increased pressure in the eye (glaucoma)
- coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- inflammation of the mouth, passing bright red blood in your stools, bad breath, inflammation of the large intestine (leading to diarrhoea)
- liver failure, yellowing of the skin or whites of
- contraction of the jaw muscle
- abnormal urine odour
- menopausal symptoms, abnormal production of breast milk in men or women
- excessive vaginal bleeding shortly after birth (postpartum haemorrhage)
- inflammation of the blood vessels in the skin (cutaneous vasculitis) the eyes (jaundice)

Children and adolescents under 18 years of age with depression treated with this medicine had some weight loss when they first start taking this medicine. Weight

increased to match other children and adolescents of their age and sex after 6 months of treatment.

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 "**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 **DUELOKS.**

5. HOW TO STORE DUELOKS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Store at or below 25 °C. Protect from moisture

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What DUELOKS contains:

DUELOKS 30

(Colourants: FD and C Blue 2 aluminium lake, yellow iron oxide), gelatin, Hypromellose, Hypromellose phthalate, propylene glycol, shellac, starch, sugar spheres, talc, titanium dioxide triethyl citrate.

Contains: sucrose 51.5mg.

DUELOKS 60

(Colourants: FD and C Blue 2 aluminium lake, yellow iron oxide.), Hypromellose, Hypromellose phthalate, iron oxide yellow, propylene glycol, potassium hydroxide, methylene chloride, shellac, starch, talc, titanium dioxide triethyl citrate.

Contains: sucrose 103 mg

What DUELOKS looks like and contents of the pack:

DUELOKS 30 (Capsule) Opaque Blue/ Opaque White Hard Gelatin Capsules size “3” having imprinting “157” on body with green ink and “A” on cap with green ink filled with white to off-white coloured pellets.

DUELOKS 60 (Capsule) Opaque Blue/ Opaque Green Hard Gelatin Capsules size “1” having imprinting “158” on body with white ink and “A” on cap with white ink filled with white to off-white coloured pellets.

Contents of Pack:

DUELOKS 30 mg: 28 capsules in Alu/Alu blister pack (Aluminium foil and cold form blister foil) or Aluminium foil and clear transparent PVC/ Aclar film blister pack.

Strips with a package insert are placed in a unit carton.

DUELOKS 60 mg: 28 capsules in Alu/Alu blister pack (Aluminium foil and cold form blister foil or Aluminium foil and clear transparent PVC/ Aclar film blister pack.

Strips with a package insert are placed in a unit carton.

Holder of Certificate of Registration

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2091

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DUELOKS 60: 52/1.2/0922

Access to the corresponding Professional information is contained in the packaging of **DUELOKS**.

Follow the link for the corresponding Professional Information for **DUELOKS**:

pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below: