PATIENT INFORMATION LEAFLET

Information for the Patient about DULOXETINE MR UNICORN

SCHEDULING STATUS:

Schedule 5.

DULOXETINE MR 30 UNICORN (33,66 mg **duloxetine**) Hard Gastro Resistant Capsules.

DULOXETINE MR 60 UNICORN (67,32 mg **duloxetine**) Hard Gastro Resistant Capsules.

Contains sugar: lactose monohydrate.

Read all of this leaflet carefully before you start taking DULOXETINE MR UNICORN 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 MR UNICORN** 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 MR UNICORN is and what it is used for

2. What you need to know before you take DULOXETINE MR UNICORN

3. How to take DULOXETINE MR UNICORN

4. Possible side effects

5. How to store DULOXETINE MR UNICORN

6. Contents of the pack and other information

1. What DULOXETINE MR UNICORN is and what it is used for

DULOXETINE MR UNICORN is used in adults to treat:

- Depression,
- Diabetic nerve pain (pain associated with the damage of nerves, described as burning, electric shock, numbness and/or tingling in limbs. The affected area may have a loss of feeling or sensations, such as touch, heat, cold or pressure).

2. What you need to know before you take DULOXETINE MR UNICORN

Do NOT take DULOXETINE MR UNICORN:

- If you are hypersensitive (allergic) to duloxetine or any of the other ingredients of **DULOXETINE MR UNICORN** (see "**What DULOXETINE MR UNICORN contains**").

- If you are taking, or have taken within the last 14 days, a medicine known as a monoamine oxidase inhibitor (for example, moclobemide or linezolid).
- If you are pregnant, planning to have a baby or breastfeeding your baby (see "**Pregnancy and breastfeeding**").
- If you have been diagnosed with severe liver damage, because **DULOXETINE MR UNICORN** is known to damage the liver.
- If you have been diagnosed with severe kidney disease.
- If you have been diagnosed with uncontrolled high blood pressure.

Warnings and precautions:

Thoughts of suicide or self-harm:

The thoughts or feelings of self-harm is normally associated with depression. The risk of these feelings or thoughts may be increased when first starting therapy with anti-depressants such as **DULOXETINE MR UNICORN**, or when your dosage is changed. These feelings normally subside during therapy.

You may be more likely to feel/think like this if you:

- have a history of having these thoughts about killing or harming yourself, and/or
- are under the age of 25 years old.

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

It is helpful to tell a caregiver (relative or close friend) if you have been diagnosed with depression or an anxiety disorder, and ask them to read this leaflet. They will be

able to inform your doctor if your depression or anxiety worsens, or if they notice unusual changes in your behaviour.

- **DULOXETINE MR UNICORN** may cause dilation of the pupils, if you have been diagnosed with eye problems such as glaucoma (increased pressure in the eye).
- If you have been diagnosed with bipolar disorder (a condition characterised by elevated moods with episodes of depression); or have a history of seizures (fits) or mania episodes (over activity, racing thoughts and decreased need for sleep).
- Tell your doctor if you have high blood pressure.
- If you are using **DULOXETINE MR UNICORN**, with or without other medicines used for depression (see "**Taking DULOXETINE MR UNICORN with other medicines**"), you may be at risk of experiencing a condition known as Serotonin Syndrome. The signs and symptoms of this condition include agitation, hallucinations, increased heart rate, fever, twitching and/or spasms, nausea, vomiting and diarrhoea. Consult your doctor if you experience these signs and symptoms.
- If you are taking medicines that contain St. John's Wort (*Hypericum perforatum*). This is a herbal preparation used in the treatment of depression.
- If you have been diagnosed with a bleeding disorder (when you bruise or bleed easily), and if you are using medicines known to thin the blood (for example, aspirin and non-steroidal anti-inflammatory drugs (NSAIDs)).
- **DULOXETINE MR UNICORN** may decrease blood sodium levels. Patients at risk are those using diuretics (water tablets) and the elderly (older than 65

years old).

- **DULOXETINE MR UNICORN** may cause a feeling of restlessness or an inability to sit or stand still. You should tell your doctor if this sensation occurs.

Children

DULOXETINE MR UNICORN should not be used in children or adolescents under the age of 18 years as the safety and effectiveness of **DULOXETINE MR UNICORN** in this population has not been established.

Other medicines and DULOXETINE MR UNICORN

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

(This includes complementary or traditional medicines.)

Please discuss the use of the following medicines or substances in combination with **DULOXETINE MR UNICORN** with your doctor or pharmacist:

- Monoamine oxidase inhibitors (MAOIs): Taking a MAOI together with **DULOXETINE MR UNICORN**, can cause serious or even life-threatening side effects. You must wait at least 14 days after you have stopped taking a MAOI before you start using **DULOXETINE MR UNICORN**. Also, you need to wait at least 5 days after you stop using **DULOXETINE MR UNICORN** before you take a MAOI. Examples of MAOIs include moclobemide (an antidepressant) and linezolid (an antibiotic).
- Medicines that inhibit the metabolism of **DULOXETINE MR UNICORN**: These medicines will increase the concentration of duloxetine in the blood, which will

increase the risk of side effects associated with **DULOXETINE MR UNICORN**. These medicines include anti-depressants, fluvoxamine and paroxetine; and quinolone antibiotics (such as ciprofloxacin and enoxacin).

- Medicines that are metabolised by the enzyme CYP2D6: **DULOXETINE MR UNICORN** may prevent the metabolism of these medicines, therefore increasing their concentrations. Examples of these medicines include desipramine, risperidone and tricyclic antidepressants (such as amitriptyline).
- Medicines that cause sleepiness: The effects of these medicines when used with **DULOXETINE MR UNICORN** is enhanced. These include medicines such as benzodiazepines (such as diazepam and lorazepam), anti-psychotics (such as chlopromazine and haloperidol), phenobarbital and antihistamines (such as chlorpheniramine).
- Oral anticoagulants or antiplatelet agents: These are medicines which thin the blood or prevent the blood from clotting (such as aspirin, warfarin and NSAIDs). **DULOXETINE MR UNICORN** may increase your risk of bleeding when used with these medicines.
- Medicines that increase the level of serotonin: Triptans, tramadol, tryptophan, SSRIs (such as paroxetine), SNRIs (such as venlafaxine), tricyclic antidepressants (such as clomipramine, amitriptyline), pethidine, St John's Wort and MAOIs (such as moclobemide and linezolid). When used with **DULOXETINE MR UNICORN**, there is an increased the risk of side effects (see "**Take Special Care with DULOXETINE MR UNICORN**") .

- Cigarette smoking: If you smoke tobacco cigarettes, the concentration of **DULOXETINE MR UNICORN** is decreased, and therefore the effect of **DULOXETINE MR UNICORN** is not sufficient for treatment of your condition.

DULOXETINE MR UNICORN with food and drink:

DULOXETINE MR UNICORN can be taken with or without food.

Precautions should be taken when consuming alcohol while taking **DULOXETINE MR UNICORN,** as the effects of duloxetine may be enhanced.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Pregnancy:

- Do not take **DULOXETINE MR UNICORN** if you are pregnant.
- If you are pregnant, or intend on falling pregnant, inform your doctor before using **DULOXETINE MR UNICORN**.
- If you take **DULOXETINE MR UNICORN** during pregnancy, you may increase the risk of a serious condition in babies, called Persistent Pulmonary Hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish in colour. If this happens to your baby you should contact your doctor immediately.
- If you take **DULOXETINE MR UNICORN** near the end of your pregnancy, your baby might have some symptoms when it is 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, contact your doctor or midwife immediately.

Breastfeeding:

- Do not use **DULOXETINE MR UNICORN** if you are breastfeeding your baby, because this medicine passes into the breast milk.

Fertility:

- **DULOXETINE MR UNICORN** may affect female fertility at high dosages.

Driving or using machinery: DULOXETINE MR UNICORN may cause dizziness, sedation and drowsiness. Therefore, you should not drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether **DULOXETINE MR UNICORN** affects your ability to perform such activities.

DULOXETINE MR UNICORN contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE DULOXETINE MR UNICORN:

Do not share medicines prescribed for you with any other person.
Always take **DULOXETINE MR UNICORN** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Oral

Adults:

For depression and diabetic neuropathic pain:

The usual starting and maintenance dose of **DULOXETINE MR UNICORN** is 60 mg once a day, with or without a meal.

Your doctor may increase your dose, if required.

Do not exceed the recommended daily dosage.

If you take more DULOXETINE MR UNICORN 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.

Signs and symptoms of overdose include impaired coordination, convulsions, decreased appetite, vomiting and fits.

Always take **DULOXETINE MR UNICORN** as prescribed (see **"HOW TO TAKE DULOXETINE MR UNICORN"**). If you have missed a dose, take it as soon as you remember. Do not take a double dose of **DULOXETINE MR UNICORN** to make up for forgotten individual doses.

If you forget to take DULOXETINE MR UNICORN:

Always take **DULOXETINE MR UNICORN** as prescribed (see **"HOW TO TAKE DULOXETINE MR UNICORN"**). If you have missed a dose, take it as soon as you remember. Do not take a double dose of **DULOXETINE MR UNICORN** to make up for forgotten individual doses.

If you stop taking DULOXETINE MR UNICORN:

DO NOT stop taking **DULOXETINE MR UNICORN** without discussing this with your doctor, even if you feel better. If your doctor thinks that you should stop using **DULOXETINE MR UNICORN**, he/she will reduce your dose gradually over at least 2 weeks and then stop treatment completely.

If you stop taking **DULOXETINE MR UNICORN** suddenly, you may experience the following withdrawal symptoms:

- feeling anxious or agitated,
- diarrhoea,
- dizziness,
- headaches,
- excessive sweating,
- feeling irritable,
- muscle pain,
- nausea and/or vomiting,
- tingling feeling ("pins and needles") or electric shock-like feelings (especially in the head),
- sleep disturbances (intense dreams, nightmares, inability to sleep),
- drowsiness,
- shaking (tremor), or
- vertigo (feeling of dizziness or "spinning").

These symptoms usually occur within a few days of stopping treatment and usually take up to 2 weeks to disappear. If these symptoms worry you, contact your doctor for advice.

4. POSSIBLE SIDE EFFECTS:

DULOXETINE MR UNICORN can have side effects.

Not all side-effects reported for DULOXETINE MR UNICORN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side-effects are frequently experienced with the use of **DULOXETINE MR UNICORN**:

- Decrease in appetite;
- Unusual dreams, feeling agitated and anxious, difficulty or failure to experience orgasm, trouble sleeping and low sex drive;
- Dizziness, headache, feeling sluggish, tingling of the skin ("pins and needles"), drowsiness and tremor;
- Blurred vision;
- Ringing sound in the ears;
- Palpitations (sensation of the heart pounding or racing);
- Increase in blood pressure and flushing (red in the face);
- Increased yawning;
- Stomach pain, constipation, diarrhoea, dry mouth, heartburn or indigestion, flatulence (breaking wind), nausea and vomiting;
- Rash and increased sweating;
- Muscle spasm and muscle pain;
- Painful urination and frequent urination;

- Changes/problems in ejaculation and problems getting an erection;
- Falls and fatigue; and
- Weight loss.

Other less frequent side effects associated with the use of **DULOXETINE MR UNICORN** include:

- Inflammation of the throat that causes a hoarse or loss of voice;
- Serious allergic reactions which causes swelling of the face or throat (angioedema) resulting in difficulty in breathing or dizziness with swollen tongue or lips, and allergic reactions;
- Decreased thyroid gland activity (This can cause tiredness or weight gain);
- Dehydration, increased blood sugar levels, low levels of sodium in the blood (especially in elderly people; the symptoms may include nausea, vomiting, headache, feeling confused, drowsiness, muscle weakness, fainting, fits or falls) and syndrome of inappropriate secretion of anti-diuretic hormone (SIADH);
- Aggression and anger, lack of interest, grinding or clenching the teeth, feeling disorientated, hallucinations, mania (over activity, racing thoughts and decreased need for sleep), difficulty sleeping, and suicidal behaviour and thoughts;
- Difficulty controlling movement e.g. lack of coordination or involuntary movements of the muscles, fits, difficulty concentrating, changes in sense of taste, involuntary muscle movement, restlessness, inability to sit or stand still, feeling nervous, restless legs syndrome, poor sleep quality and Serotonin syndrome (a rare reaction which may cause agitation, hallucinations,

increased heart rate, fever, twitching and/or spasms, nausea, vomiting and diarrhoea.);

- Increased pressure in the eye (glaucoma), large pupils (the dark centre of the eye) and problems with eyesight;
- Ear pain and vertigo (feeling of dizziness or “spinning”);
- Fast and/or irregular heart beat;
- Increased blood pressure, light-headedness or fainting when standing up, cold fingers and/or toes and fainting;
- Nose bleeds and throat tightness;
- Bad breath, difficulty swallowing, burping, inflammation of the stomach lining causing vomiting of blood, or black tarry stools (faeces), gastroenteritis and passing bright red blood in your stools and inflammation of the mouth;
- Inflammation of the liver that may cause abdominal pain and yellowing of the skin or white part of the eyes and liver failure;
- Cold sweats, increased tendency to bruise, night sweats, sensitivity to sunlight, Stevens-Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals) and hives;
- Muscle tightness, muscle twitching and lock-jaw (contraction of the jaw muscle);
- Abnormal urine odour, needing to pass urine during the night, needing to pass more urine than normal, difficulty to start urinating, difficulty or inability to pass urine and having a decreased urine flow;
- Abnormal production of breast milk in men or women, menopausal symptoms, abnormal periods (including heavy, painful, irregular or prolonged periods), sexual dysfunction, and pain in the testicles or scrotum;

- Chest pain, shivering, feeling cold and/or hot, abnormal movement of the limbs and thirst; and
- Weight gain.

DULOXETINE MR UNICORN 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 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.

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd to

enquiries@unicornpharma.co.za

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

5. How to store DULOXETINE MR UNICORN

Store at or below 25 ºC.

Protect from moisture.

Store in the original packaging.

Do not take after the expiry date stated on the package.

Return all unused **DULOXETINE MR UNICORN**to your pharmacist.

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

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What DULOXETINE MR UNICORN contains

The active substance is DULOXETINE.

The other ingredients are: Gelatin, Hypromellose HPMC 2910, Lactose Monohydrate, Macrogel, Magnesium stearate, Microcrystalline cellulose (type 102), Povidone, Starch Maize (pregelatinised), Sodium Stearate Fumarate, Talc and Titanium dioxide.

DULOXETINE MR UNICORN contains sugar (lactose monohydrate).

What DULOXETINE MR UNICORN looks like and contents of the pack

DULOXETINE MR 30 UNICORN: Opaque dark blue cap-opaque white body printed with “30”, size 2 hard gelatin capsules, containing 4 white to off white, round, biconvex tablets per capsule.

DULOXETINE MR 60 UNICORN: Opaque dark blue cap-opaque yellowish green body printed with “60”, size OE hard gelatin capsules, containing 8 white to off white, round, biconvex tablets per capsule .

DULOXETINE MR UNICORN hard gastro-resistant capsules are available in

(PVC/PE/PCTFE/AI or PA/Al/PVC/AI) blisters in a cardboard box.

Pack sizes:

DULOXETINE MR 30 UNICORN: 7, 28 and 98 capsules.

DULOXETINE MR 60 UNICORN: 28, 56, 84, 98, 100 and 500 capsules.

DULOXETINE MR UNICORN hard gastro-resistant capsules are available in

HDPE bottles with child-resistant PP screw cap in a cardboard box.

Pack size:

DULOXETINE MR 30 UNICORN & 60: 30 capsules.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets

Cape Town

8001

Application number(S)

DULOXETINE MR UNICORN 100: 540589

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