PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

PAROXETINE UNICORN 20 mg tablets

Paroxetine

Read all of this leaflet carefully before you start taking PAROXETINE UNICORN 20.

- 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.
- **PAROXETINE UNICORN 20** 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 **PAROXETINE UNICORN 20** is and what it is used for
2. What you need to know before you take **PAROXETINE UNICORN 20**
3. How to take **PAROXETINE UNICORN 20**
4. Possible side effects
5. How to store **PAROXETINE UNICORN 20**
6. Contents of the pack and other information

1. What PAROXETINE UNICORN 20 is and what it is used for

PAROXETINE UNICORN 20 is used to treat a variety of emotional problems.

- **Depression**

  Continuing depression that interferes with your ability to function.

- **Obsessive compulsive disorder (OCD)**

  A condition identified by unwanted, but stubbornly persistent thoughts, and/or unreasonable rituals you feel compelled to repeat.

- **Social Phobia**

  A condition characterised by a strong fear of being judged by others, of being embarrassed and marked by shyness or stage fright so intense that it interferes with your work and social life.

- **Panic Disorder**

  A crippling emotional problem characterised by sudden attacks of at least four of the following symptoms: rapid heartbeat, sweating, shaking, numbness, chills or hot flashes, shortness of breath, a feeling of choking, chest pain, nausea or abdominal distress, dizziness or faintness, feelings of unreality or detachment, fear of losing control, or fear of dying.

- **Generalised Anxiety Disorder:**

  A disease marked by excessive anxiety and worry that persists for at least 6 months and cannot be easily controlled. True cases of generalised anxiety disorder are accompanied by at least three of the following symptoms: restlessness or an on-edge feeling, a tendency to wear out easily, difficulty concentrating or spells when the mind goes blank, irritability, muscle tension, or sleep disturbance.

2. What you need to know before you take PAROXETINE UNICORN 20

Do not take PAROXETINE UNICORN 20:

- if you are hypersensitive (allergic) to paroxetine or any of the other ingredients of **PAROXETINE UNICORN 20** (listed in section 6). If you are unsure about this, ask your doctor (see **"What PAROXETINE UNICORN 20 contains"**).
- If you are taking other medicines for depression called monoamine oxidase inhibitors (MAOIs, including moclobemide and linezolid), or have taken them at any time within the last two weeks. Your doctor will advise you how you should begin taking **PAROXETINE UNICORN 20** once you have stopped taking the MAOI. You should also not start taking MAO inhibitors for two weeks after **PAROXETINE UNICORN 20** treatment is terminated.
- **PAROXETINE UNICORN 20** should not be used for children and adolescents under the age of 18 years. (see **Take special care with PAROXETINE UNICORN 20**).
- If you have epilepsy or a history of seizures / fits.
- If you are taking a medicine containing pimozide (to treat a mental disorder), as **PAROXETINE UNICORN 20** may cause a serious irregular heart beat which can be fatal when taken in combination with these medicines.
- If you have porphyria (an enzyme disorder with symptoms such as severe abdominal pain, pain in your chest, back or legs, vomiting or a rapid heartbeat).

Warnings and precautions

Take special care with PAROXETINE UNICORN 20:

- If you are an adolescent or young adult aged less than 18 years.
- 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 antidepressants, since these medicines take time to work, (usually about two weeks but sometimes longer).
- Your doctor will monitor your treatment and your progress carefully for the first few weeks. If you have any thoughts of harming or killing yourself at any time, contact your doctor immediately or go to a hospital straight away.
- Do not stop taking **PAROXETINE UNICORN 20** without telling your doctor. If you stop taking your **PAROXETINE UNICORN 20** tablets suddenly, you may experience withdrawal effects (see “Possible side effects”)
- If you suffer from epilepsy or seizures (fits).
- If you experience a feeling of restlessness, usually within the first few weeks of treatment (see “Possible side effects”).
- If you are taking other similar medicines for a mental condition as this may lead to Neuroleptic Malignant Syndrome, a life-threatening condition with symptoms such as rigid muscles and fever.
- If you take medicines containing oxitriptan or L-tryptophan (to treat mood disorders) as you may be at risk of serotonergic syndrome (a condition with symptoms such as agitation or restlessness, dilated pupils and heavy sweating)
- If you have episodes of mania (overactive behaviour or thoughts).
- If you are taking medicine to prevent the clotting of blood or are prone to bleed easily as **PAROXETINE UNICORN 20** may increase the risk of bleeding. Talk to your doctor before

taking **PAROXETINE UNICORN 20** if you have a history of bleeding disorders or if you are pregnant (see **Pregnancy and breastfeeding and fertility**).

- If you take a medicine containing risperidone (to treat a mental disorder), as this may lead to toxicity (see "**Other medicines and PAROXETINE UNICORN 20").**
- If you are taking alcohol as **PAROXETINE UNICORN 20** should not be taken with alcohol.
- If you experience unexplained bone pain, tenderness, swelling or bruising. **PAROXETINE UNICORN 20** may be associated with bone fractures.
- If you have a heart disorder.
- If you suffer from glaucoma (an eye condition that can result in the damage of the optic nerve).
- If you have diabetes, as the dosage of you medicine may have to be adjusted.
- If you have kidney or liver problems.
- If you are or planning to become pregnant, as the use of **PAROXETINE UNICORN 20** during the first three months of pregnancy, may cause heart defects in the infant (see **Pregnancy and breastfeeding and fertility**").

Children and adolescents under 18

PAROXETINE UNICORN 20 must not be used for children and adolescents under 18 years. 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 **PAROXETINE UNICORN 20**.

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.

Other medicines and PAROXETINE UNICORN 20:

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **PAROXETINE UNICORN 20** with these medicines may cause undesirable interactions.

Some of the medicines that may interact with **PAROXETINE UNICORN 20** are:

- Medicines called monoamine oxidase inhibitors (MAOIs) including moclobemide (see **Do not take PAROXETINE UNICORN 20**)
- Debrisoquine (a medicine used to treat high blood pressure) as **PAROXETINE UNICORN 20** may increase debrisoquine's effect.
- Risperidone (used to treat psychiatric conditions) as **PAROXETINE UNICORN 20** may increase the effect of risperidone.
- Phenytoin or phenobarbitone (used in the treatment and prevention of seizures in epilepsy) may decrease the effect of **PAROXETINE UNICORN 20** and lead to symptoms such as diarrhoea and nervousness.
- Pimozide (used to treat schizophrenia) as **PAROXETINE UNICORN 20** may cause a serious irregular heart beat when taken in combination with these medicines.
- Procyclidine (used to treat Parkinsonism) as **PAROXETINE UNICORN 20** may increase the effect of procyclidine.
- Aspirin, ibuprofen or other medicines called NSAIDs (non-steroidal anti- inflammatory medicines) used for pain and inflammation.
- Sumatriptan (used to treat migraine).
- Theophylline (used in the treatment of asthma).

- Tamoxifen (used to treat breast cancer) as **PAROXETINE UNICORN 20** may reduce the effect of tamoxifen.
- Digoxin (used in the treatment of heart failure) as **PAROXETINE UNICORN 20** may decrease the effect of digoxin.
- Cimetidine (a medicine used to treat heart burn and stomach ulcers) may increase the effect of **PAROXETINE UNICORN 20**.
- Spartein (used to treat heart conditions) as **PAROXETINE UNICORN 20** may increase the effect of this medicine.
- Lithium (used to treat depression) as **PAROXETINE UNICORN 20** may increase the effect of this medicine.
- Fentanyl (used in general anaesthesia) and tramadol or pethidine (for pain).
- Propafenone (used to treat an irregular heartbeat) or metoprolol used to treat high blood pressure as **PAROXETINE UNICORN 20** may increase the effect of these medicines.
- Tryptophan (an amino acid supplement), linezolid (an antibiotic), other SSRI's or St John's Wort (sometimes used for depression) as taking these medicines with **PAROXETINE UNICORN 20** may lead to a condition called "serotonin syndrome" with symptoms such as fits, shaking, restlessness and irritability.
- Warfarin or other medicines preventing blood clots as the use of **PAROXETINE UNICORN 20** may result in bleeding.
- Tricyclic antidepressants such as clomipramine, nortriptyline, amitriptyline, imipramine and desipramine as **PAROXETINE UNICORN 20** may increase the effect of tricyclic antidepressants.
- The effect of **PAROXETINE UNICORN 20** is not affected, or only marginally affected by food, antacids and propranolol.

PAROXETINE UNICORN 20 with food, drink and alcohol

PAROXETINE UNICORN 20 tablets should be taken once a day in the morning with food and should be swallowed not chewed.

Do not drink alcohol while you are taking **PAROXETINE UNICORN 20**. Alcohol may worsen your side effects.

Pregnancy and breastfeeding and fertility

The safe use of **PAROXETINE UNICORN 20** during pregnancy and breastfeeding has not been established. 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.

If you are already taking **PAROXETINE UNICORN 20** and have just found out that you are pregnant you should talk to your

healthcare provider immediately. This is because some studies have suggested an increase in the risk of heart defects in babies whose mothers received **PAROXETINE UNICORN 20** in the first few months of pregnancy.

Your healthcare provider may decide that it is better for you to gradually stop taking **PAROXETINE UNICORN 20** while you are pregnant.

The use of **PAROXETINE UNICORN 20** in pregnancy, particularly in late pregnancy, may have an increased risk of persistent pulmonary hypertension of the new-born (PPHN), with symptoms such as rapid breathing, lack of oxygen, heart problems.

If you take **PAROXETINE UNICORN 20** near the end of your pregnancy there may be an increased risk of heavy 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 **PAROXETINE UNICORN 20** so that they can advise you.

Driving and using machines

It is not always possible to predict to what extent **PAROXETINE UNICORN 20** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **PAROXETINE UNICORN 20** affects them. **PAROXETINE UNICORN 20** may cause drowsiness and dizziness. Make sure you know how you react to **PAROXETINE UNICORN 20** before driving a vehicle, operating machinery, or do anything else that could be dangerous.

3. How to take PAROXETINE UNICORN 20

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

Always take **PAROXETINE UNICORN 20** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one **PAROXETINE UNICORN 20** tablet (20 mg paroxetine) once a day in the morning, with food. The tablet should be swallowed and not chewed. Your doctor will advise you on your tablet dose, based on your specific condition.

The safety and efficacy of **PAROXETINE UNICORN 20** in children under the age of 18 years have not been established. **PAROXETINE UNICORN 20** should therefore not be used in the treatment of children and adolescents under the age of 18 years.

Take your tablets once a day, every day, at about the same time each day.

Your doctor will tell you how long your treatment with **PAROXETINE UNICORN 20** will last. Do not stop treatment early because you may experience withdrawal symptoms (see "If you stop taking **PAROXETINE UNICORN 20"**).

If you have the impression that the effect of **PAROXETINE UNICORN 20** is too strong or too weak, tell your doctor or pharmacist.

If you take more PAROXETINE UNICORN 20 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 may include vomiting, dilated pupils, fever, headache, rapid heartbeat, muscle contractions and feeling anxious. Do not forget to take the product pack with you, as well as the remaining tablets.

If you forget to take a dose of PAROXETINE UNICORN 20:

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time. **Do not take a double dose.**

If you stop taking PAROXETINE UNICORN 20:

Feeling dizzy or shaky (tremors), sleep disturbances, anxiety, headache, nausea, feeling confused, excessive sweating, diarrhoea.

4. Possible side effects

PAROXETINE UNICORN 20 can have side effects.

Not all side effects reported for **PAROXETINE UNICORN 20** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **PAROXETINE UNICORN 20**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **PAROXETINE UNICORN 20** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Chest pain
- rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **PAROXETINE UNICORN 20**. 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:

- abnormal bleeding of the skin, eye or stomach, purpura (purple spots on the skin caused by internal bleeding from the blood vessels)
- various conditions which can only be detected by means of laboratory tests of the blood, urine and heart
- thinking of killing yourself (suicidal ideation) and suicidal behaviour
- blurred or abnormal vision, dilation of pupils or glaucoma (high eye pressure)
- fast irregular heartbeat
- high blood pressure or low blood pressure (feeling dizzy when standing up)
- Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters)
- chest pain, difficulty in breathing

- inflammation of the liver (hepatitis) with symptoms such as fatigue, loss of appetite and muscle, joint ache or liver failure
- yellowing of the skin and eyes, also called jaundice
- seizures, shivering rapid or slow heartbeat,
- lack of ability to urinate, loss of bladder control, bladder infection

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:

- bruising
- decreased or increased appetite, weight gain or loss
- drowsiness, feeling dizzy or shaky (tremors), headache, fatigue
- yawning, dry mouth
- diarrhoea, constipation, nausea, vomiting, heart-burn, indigestion, stomach pain, feeling bloated, excessive gas (wind)
- decreased sexual ability (sexual dysfunction)

Less frequent side effects:

- having hallucinations (strange visions or sounds), memory loss, impaired concentration, confusion, anxiety (feeling anxious especially children), depersonalisation (a feeling where your thoughts and feelings seem unreal or not to belong to yourself), panic attacks, inability to sit still, manic reactions, abnormal dreams
- migraine (very severe headache), not sleeping well (insomnia) or feeling sleepy, restlessness, nervousness, tingling or prickly
- sensation (“pins and needles”), shivering

- anisocoria (characterised by unequal size of the pupil of the eye)
- sinusitis, bronchitis, coughing, sore throat, blocked, red runny nose
- excessive sweating, skin rashes, sensitivity to sunlight
- muscle pain or weakness, joint pain, absence or decrease in body movements and bone fractures
- spontaneous flow of milk from the breasts, painful erection, painful or abnormal menstruation
- swelling of the feet and legs (peripheral oedema), feeling weak, unusual tiredness or weakness

Frequency unknown

- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see **"Pregnancy, breastfeeding and fertility**" 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 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. Side effects can also be reported directly to Unicorn Pharmaceuticals (Ply) Ltd at vigilance@unicornpharma.co.za. By reporting side effects, you can help provide more information on the safety of **PAROXETINE UNICORN 20**.

5. How to store PAROXETINE UNICORN 20.

Store all medicines out of reach of children

Store at or below 25 ºC.

Protect from light.

Do not remove blister from the carton until required for use.

Do not use after the expiry date stated on the label or carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What PAROXETINE UNICORN 20 contains

The active substance is paroxetine

Each tablet contains paroxetine hydrochloride equivalent to 20 mg paroxetine.

The other ingredients are:

Eudagrit, magnesium stearate, mannitol, microcrystalline cellulose, Opadry AMB White, sodium starch glycollate.

PAROXETINE UNICORN 20 tablets are sugar free.

What PAROXETINE UNICORN 20 looks like and contents of the pack

White to off-white, round, coated, bi-convex tablets, diameter 10 mm, scored on both walls and sides, marked “P” on one wall and “20” on the other wall, OR white, round, coated, biconvex tablets, with 10 mm diameter, scored on one face and marked "P20" on the other.

Aluminium blister packs of 30 tablets.

Each blister strip contains 10 tablets.

White cylindrical polypropylene homopolymer tube with a white natural LDPE cap, containing 30 tablets.

Holder of Certificate of Registration

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