

Applicant: Unicorn Pharmaceuticals (Pty) Ltd
Product Name: Escitalopram Unicorn 5, 10, 15, 20
Dosage form and strength: Each film coated tablet contains escitalopram oxalate equivalent to escitalopram 5 mg, 10 mg, 15 mg and 20 mg respectively.

CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

ESCITALOPRAM UNICORN 5 mg film coated tablets

ESCITALOPRAM UNICORN 10 mg film coated tablets

ESCITALOPRAM UNICORN 15 mg film coated tablets

ESCITALOPRAM UNICORN 20 mg film coated tablets

Escitalopram

Sugar free

Please read all of this leaflet carefully before you start taking ESCITALOPRAM UNICORN

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **ESCITALOPRAM 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 **ESCITALOPRAM UNICORN** is and what it is used for
2. What you need to know before you take **ESCITALOPRAM UNICORN**
3. How to take **ESCITALOPRAM UNICORN**
4. Possible side effects
5. How to store **ESCITALOPRAM UNICORN**
6. Contents of the pack and other information

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1. What **ESCITALOPRAM UNICORN** is and what it is used for

Escitalopram is an antidepressant which belongs to the SSRI group (selective serotonin reuptake inhibitors). These medicines act on the serotonin system in the brain by increasing the serotonin level. Disturbances in the serotonin system are considered an important factor in the development of depression and related diseases.

ESCITALOPRAM UNICORN is used for:

- Depressive disorders (Major depressive episodes)
- Panic disorder with or without agoraphobia (e.g., fear of leaving the house, entering shops, being in crowds and in public places)

2. What you need to know before you take **ESCITALOPRAM UNICORN**

Do not take ESCITALOPRAM UNICORN:

- If you are allergic (hypersensitive) to escitalopram or any of the ingredients in the formulation (see "**What ESCITALOPRAM UNICORN contains**").
- If you are born with or have had an episode of abnormal heart rhythm (seen on the electrocardiogram (ECG), which is an examination to evaluate how your heart is functioning).
- If you take medicines for heart rhythm problems or which may affect the heart's rhythm (see "**Other medicines and ESCITALOPRAM UNICORN**").
- If you are taking any other medication for depression, such as monoamine oxidase inhibitors (MAOIs). At least 14 days should elapse between stopping such medication and starting with **ESCITALOPRAM UNICORN**. MAOIs should not be started within 7 days after discontinuation of **ESCITALOPRAM UNICORN**.
- If you are pregnant or breastfeeding, do not take **ESCITALOPRAM UNICORN**.
- **ESCITALOPRAM UNICORN** should not be used by children under the age of 18 years.

Warnings and precautions

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Take special care with ESCITALOPRAM UNICORN:

- If you are an elderly person.
- If you have any liver or kidney disorder.
- If you have epilepsy (fits/seizures) or have a history thereof.
- If you receive electroconvulsive therapy for the treatment of depression.
- If you have mania or a history of mania.
- If you have a heart disorder.
- If you have diabetes (high blood sugar).
- If you have thoughts of harming yourself or committing suicide.
- If you have a tendency to easily develop bleedings or bruises. Talk to your doctor before taking **ESCITALOPRAM UNICORN** if you have a history of bleeding disorders.
- If you are pregnant (see “**Pregnancy and breastfeeding and fertility**”).
- If you have a panic disorder, you may experience increased anxiety symptoms at the start of your **ESCITALOPRAM UNICORN** treatment. Your doctor will therefore start you on a low dose to reduce your risk of having a panic attack.
- If you have a movement disorder characterised by a feeling of inner restlessness. Your doctor will control your dosage.
- If you have a decreased level of sodium in your blood.
- If you are taking medicines with serotonergic effects (see “**Other medicines and ESCITALOPRAM UNICORN**”).
- If you suffer from a heart condition called QT prolongation or if the condition runs in your family.
- If you have a low resting heart rate.
- If you have low levels of potassium or magnesium in your blood (hypokalaemia/hypomagnesaemia).
- If you are using St John’s wort, as it may result in an increased incidence of adverse reactions.
- If you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

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Other medicines and ESCITALOPRAM UNICORN

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

The following may cause an interaction with **ESCITALOPRAM UNICORN**:

- Linezolid, sparfloxacin, moxifloxacin, erythromycin or pentamidine (used to treat bacterial infections).
- Selegiline (used to treat early-stage Parkinson's disease, depression or memory loss).
- Imipramine, desipramine, clomipramine, moclobemide, nortriptyline, amitriptyline, fluoxetine, paroxetine, sertraline or bupropion (used to treat depression).
- Tramadol (used to treat moderate to severe pain), sumatriptan (used to treat migraine) and other triptans (used to treat migraine or cluster headaches).
- Avoid the consumption of alcohol.
- Warfarin (used to prevent blood from clotting).
- Cimetidine or omeprazole (used to treat stomach ulcers or heartburn).
- Antidysrhythmics e.g., quinidine, procainamide, amiodarone, sotalol, metoprolol, flecainide or propafenone (used to treat abnormal heart rhythms).
- Chlorpromazine, fluphenazine, chlorprothixene (used to treat various psychiatric disorders, including schizophrenia).
- Haloperidol (used in the treatment of schizophrenia, acute psychosis, mania, intractable hiccups, agitation and severe anxiety).
- Halofantrine or mefloquin (used to treat malaria).
- Astemizole or mizolastine (used to treat allergies, hives (urticaria) and other allergic conditions).
- Lithium (used to treat bipolar disorders).
- St John's wort (a complementary medicine of herbal origin, used to treat depression).
- Nonsteroidal anti-inflammatory medicines, e.g., ibuprofen, diclofenac or aspirin (used to treat pain and inflammation).

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- Risperidone, thioridazine (used to treat certain mental or mood disorders, such as schizophrenia or bipolar disorder).
- Medicines that decrease blood levels of potassium or magnesium, as these conditions increase the risk of life-threatening heart rhythm disorders.

ESCITALOPRAM UNICORN with food and drink:

The **ESCITALOPRAM UNICORN** tablets can be taken with or without food.

Pregnancy and breastfeeding and fertility

DO NOT take **ESCITALOPRAM UNICORN** if you are pregnant or suspect that you are pregnant.

If you take **ESCITALOPRAM UNICORN** 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 **ESCITALOPRAM UNICORN** so that they can advise you.

DO NOT take **ESCITALOPRAM UNICORN** if you are 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 healthcare provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent **ESCITALOPRAM UNICORN** 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 **ESCITALOPRAM UNICORN** affects them. **ESCITALOPRAM UNICORN** may impair your ability to drive and use machinery. Do not drive a vehicle or use machinery if you feel dizzy, tired or drowsy while taking **ESCITALOPRAM UNICORN**. Please make sure you know how **ESCITALOPRAM UNICORN** affects you before driving or using machinery.

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3. How to take ESCITALOPRAM UNICORN

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

Your doctor and you should talk about the benefits and risks of treatment with **ESCITALOPRAM UNICORN**.

Always take **ESCITALOPRAM UNICORN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

To treat depression

The recommended dosage of **ESCITALOPRAM UNICORN** is 10 mg once a day in otherwise healthy adults either in the morning or the evening, with or without food. The dose can be increased to a maximum of 20 mg per day by your doctor.

To treat panic disorders, with or without agoraphobia

The starting dose of **ESCITALOPRAM UNICORN** is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day.

The dose of **ESCITALOPRAM UNICORN** will be different for different patients and may depend on a number of factors, including what the medicine is being used for, whether or not other medicines are also being taken, and if you are elderly or suffer from kidney or liver damage or injury.

Duration of treatment

It may take a couple of weeks before you start to feel better. Continue to take **ESCITALOPRAM UNICORN** even if it takes some time before you feel any improvement in your condition. Do not change the dose of your medicine without talking to your doctor first.

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Continue to take **ESCITALOPRAM UNICORN** for as long as your doctor recommends. If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.

If you have the impression that the effect of **ESCITALOPRAM UNICORN** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ESCITALOPRAM UNICORN than you should

In the event of overdose, consult your doctor or pharmacist, if neither is available, seek help at the nearest hospital or poison centre. Take this leaflet and the remaining tablets with you so the doctor will know what you have taken.

Symptoms of overdose may include dizziness, shaking, restlessness, feeling sleepy, unconsciousness, change in heart rhythm, fits, hypoventilation, muscle weakness, tenderness or pain and feeling unwell or have a high temperature (rhabdomyolysis), change in body fluid/salt balance, vomiting (being sick).

If you forget to take ESCITALOPRAM UNICORN

Do not take a double dose to make up for forgotten doses. If you forget to take a dose of **ESCITALOPRAM UNICORN**, take your dose as usual at the next scheduled time.

If you stop taking ESCITALOPRAM UNICORN

If you want to interrupt your **ESCITALOPRAM UNICORN** treatment, please discuss this with your doctor beforehand. He/she may need to take appropriate measures. Do not stop taking **ESCITALOPRAM UNICORN** on your own initiative without discussing this with your doctor. When stopping treatment with **ESCITALOPRAM UNICORN**, your doctor will gradually reduce your dose over a number of weeks or months. This should help reduce the possibility of withdrawal effects.

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When you stop taking **ESCITALOPRAM UNICORN**, especially if it is abruptly, you may experience discontinuation symptoms. These are common when treatment with **ESCITALOPRAM UNICORN** is stopped. The risk is higher when **ESCITALOPRAM UNICORN** has been used for a long time or in high doses or when the dose is reduced too quickly. Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2 - 3 months or more). If you experience severe discontinuation symptoms when you stop taking **ESCITALOPRAM UNICORN**, please contact your doctor. He/ she may ask you to start taking your tablets again and then reduce your dosage gradually.

Discontinuation symptoms include: Feeling dizzy (unsteady or off-balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea) and vomiting, sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

4. Possible side effects

ESCITALOPRAM UNICORN may have side effects. Not all side effects reported for **ESCITALOPRAM UNICORN** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **ESCITALOPRAM UNICORN**, please consult your health care provider for advice.

If any of the following happens, stop taking **ESCITALOPRAM UNICORN** 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.
- Rash, itching, urticaria (hives).

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- Fainting.

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

Less frequent:

- Seizures (fits).
- Symptoms of serotonin syndrome, characterised by high fever, agitation, confusion, trembling and abrupt contractions of muscles.
- Fast or slow irregular heartbeat and/or fainting, which could be symptoms of a life-threatening condition known as torsades de pointes.

Frequency unknown:

- Difficulty urinating.
- Yellowing of your skin and the white in your eyes are signs of liver function impairment, also called jaundice.

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Anxiety, restlessness and abnormal dreams.
- Decreased or increased appetite or weight gain.
- Sleeping problems (insomnia), sleepiness (somnolence), dizziness, unusual weakness, headache, burning or prickling sensation (paraesthesia), involuntary shaking of your body or limbs (tremor).
- Blocked or runny nose (sinusitis), yawning.
- Feeling sick (nausea), vomiting (being sick), constipation, diarrhoea, dry mouth, indigestion and/or bloatedness.

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- Increased sweating.
- Fatigue and fever.
- Muscle and/or joint pain.
- Sexual disturbances (delayed ejaculation, problem with erection), decreased sexual drive, and women may experience difficulties achieving orgasm.
- High fever, swelling of soft tissues as a result of excess fluid accumulation (oedema).

Less frequent:

- Clenching and grinding of your teeth (bruxism).
- Agitation, nervousness, panic attack, confusion, aggression, loss of contact with your own personal reality accompanied by feelings of unreality (depersonalisation), seeing or feelings things that do not exist (hallucinations).
- Weight loss.
- Taste disturbance, loss of consciousness, restlessness, poor concentration, unusual tiredness, movement disorders (involuntary movements of the muscles), inability to sit still (akathisia).
- Enlarged pupils (mydriasis), blurred vision, ringing in the ears (tinnitus).
- Nose bleed (epistaxis).
- Blood in your stools.
- Hair loss (temporary).
- Bleeding from the uterus that is not associated with menstruation, abnormally heavy or extended menstrual flow.
- Flow of milk in women that are not nursing.
- Painful erection of the penis.

Frequency unknown:

- Bleeding disorders including skin and mucous bleeding (ecchymosis) and low level of blood platelets (thrombocytopenia).
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see “**Pregnancy, breastfeeding and fertility**” for more information.

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- Build-up of fluids as well as abnormally low sodium levels (hyponatraemia).
- Anorexia.
- Elevated mood state (mania).
- Suicide related behaviour, thoughts of harming yourself or thoughts of killing yourself.
- Angry behaviour (hostility).
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension).
- Increase in saliva.
- Abnormal liver function test (increased amounts of liver enzymes in your blood).
- Lack or loss of strength and energy (asthenia).
- Increased risk of bone fractures.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found on-line under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za.

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

5. How to store ESCITALOPRAM UNICORN

- Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from light.
- Keep blister strips in outer carton until required for use.
- Do not use after the expiry date stated on the carton or blister strip.
- Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What ESCITALOPRAM UNICORN contains

Active ingredient:

ESCITALOPRAM UNICORN 5:

Each film coated tablet contains escitalopram oxalate equivalent to 5 mg escitalopram.

ESCITALOPRAM UNICORN 10:

Each film coated tablet contains escitalopram oxalate equivalent to 10 mg escitalopram.

ESCITALOPRAM UNICORN 15:

Each film coated tablet contains escitalopram oxalate equivalent to 15 mg escitalopram.

ESCITALOPRAM UNICORN 20:

Each film coated tablet contains escitalopram oxalate equivalent to 20 mg escitalopram.

Inactive ingredients:

Anhydrous colloidal silica, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, purified talc and Opadry White (containing macrogol, hypromellose and titanium dioxide).

What ESCITALOPRAM UNICORN looks like and contents of the pack

ESCITALOPRAM UNICORN 5:

White, round, biconvex, film coated tablet, debossed with 'B2' on one side and plain on the other side.

ESCITALOPRAM UNICORN 10:

White, oval shaped, biconvex, film coated tablet, with score-line on one side, debossed with 'B' on left side of score-line and '3' on right side of score-line and plain on the other side.

ESCITALOPRAM UNICORN 15:

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White, modified capsule shaped, biconvex, film coated tablet with score-line on both sides, debossed with '15' on one side of the score-line, on one side of the tablet.

ESCITALOPRAM UNICORN 20:

White, oval shaped, biconvex, film coated tablet with score-line on one side, debossed with 'B4' on side of score-line and plain on the other side.

ESCITALOPRAM UNICORN is packed into transparent PVC/PE/PVDC film / silver aluminium foil blister strips or OPA-Alu-PVC/Alu / silver aluminium foil blister strips.

10 or 14 film coated tablets are packed per blister strip.

2 x 14 tablet blister strips (28 film coated tablets) or 3 x 10 tablet blister strips (30 film coated tablets) are packed in an outer cardboard carton.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd.

Cnr. Searle & Pontac Streets,

Cape Town, 8001

South Africa

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01 August 2021

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