PROPOSED CLEAN PATIENT INFORMATION LEAFLET FOR

VENLOR XR 37,5 mg TABLET, VENLOR XR 75 mg TABLET, VENLOR XR 150 mg TABLET,

VENLOR XR 225 mg TABLET AND VENLOR XR 300 mg TABLET

SCHEDULING STATUS: S5

VENLOR XR 37,5 mg TABLET (37,5 mg prolonged-release tablets)

VENLOR XR 75 mg TABLET (75 mg prolonged-release tablets)

VENLOR XR 150 mg TABLET (150 mg prolonged-release tablets)

VENLOR XR 225 mg TABLET (225 mg prolonged-release tablets)

VENLOR XR 300 mg TABLET (300 mg prolonged-release tablets)

Venlafaxine hydrochloride

Contains sugar: lactose monohydrate 40 % *w/w.*

VENLOR XR 37,5 mg TABLET: mannitol 5,00 mg per tablet.

VENLOR XR 75 mg TABLET: mannitol 10,00 mg per tablet.

VENLOR XR 150 mg TABLET: mannitol 20,00 mg per tablet.

VENLOR XR 225 mg TABLET: mannitol 30,00 mg per tablet.

VENLOR XR 300 mg TABLET: mannitol 40,00 mg per tablet

Read all of this leaflet carefully before you start taking VENLOR XR TABLET

- 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.

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

1. What VENLOR XR TABLET is and what it is used for

VENLOR XR TABLET contains the active ingredient called venlafaxine hydrochloride. VENLOR XR TABLET belongs to a class of medicine known as Serotonin and Norepinephrine Reuptake Inhibitors (SNRI) and it is used in the treatment of depression, including depression associated with anxiety. It is also used to prevent episodes of depression from reoccurring.

2. What you need to know before you take VENLOR XR TABLET

Do not take VENLOR XR TABLET:

- if you are hypersensitive (allergic) to venlafaxine hydrochloride or any of the other ingredients of VENLOR XR TABLET (listed in **section 6**)
- if you are currently being treated with medicines which fall under a class called monoamine oxidase inhibitors (such as moclobemide)

- if you have stopped taking a medicine which falls under the class of monoamine oxidase inhibitors in less than 14 days
- if you are less than 18 years of age
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with VENLOR XR TABLET:

- if you have been diagnosed with major depressive disorder
- if you take other medicines which, when taken with VENLOR XR TABLET, could increase the risk of developing serotonin syndrome
- if you have been diagnosed with an eye condition called glaucoma
- if you have a heart condition
- if you have high blood pressure
- if you have a history of seizures (fits)
- if you have a history or family history of a mood disorder
- if you have a history of excessive anger
- if you are elderly
- if you have a tendency to bleed or bruise easily
- if you have been diagnosed with high cholesterol
- if you are diabetic
- if you take VENLOR XR TABLET you might develop a dry mouth and have a higher risk tooth decay. Good dental hygiene is advised.

Tell your doctor:

- if you develop symptoms such as an increase in heart rate, an abnormal increase in body temperature, feeling anxious, seeing things that are not there (hallucinations), nausea, vomiting and diarrhoea.
- if you are taking medicines such as lithium, sibutramine, St. John's Wort [*Hypericum perforatum*], fentanyl, tramadol, dextromethorphan, tapentadol, pethidine, methadone and pentazocine.
- if you develop a rash or any other allergic skin reaction.
- if you are taking weight loss medicines.
- if you are taking diuretic medicines/ water tablets (such as indapamide) or you have recently lost a lot of body fluids due to vomiting or diarrhoea.
- if you are taking medicines to prevent blood clots (such as warfarin) and if you are due to have surgery as VENLOR XR TABLET increases the risk of blood loss during surgery.
- if you have liver or kidney problems as your dose of VENLOR XR TABLET may need to be adjusted (see **section 3**).
- if you experience difficulty during sexual activity while taking VENLOR XR TABLET.
- if you develop symptoms such as restlessness and an inability to sit or stand still while taking VENLOR XR TABLET.
- if you develop suicidal thoughts while taking VENLOR XR TABLET.
- if you are stopping the treatment with VENLOR XR TABLET, it should be done gradually, and you should be monitored by your health care professional. Side effects which you might experience include: feeling over-excited, anxiety, agitation (restlessness), nervousness, confusion, inability to sleep and other sleeping disturbances, feeling tired, sleepiness, tingling in your limbs, feeling dizzy, fits (seizures), a feeling of losing balance, headache, flu-like symptoms (i.e. backache, sore throat), ringing in the ears, impaired co-ordination and balance, shakiness, sweating, dry mouth, loss of appetite, frequent, loose

watery stools which can cause dehydration and may require hospitalisation and treatment with intravenous fluids, nausea and vomiting. Most of these side effects are mild and will go away without treatment.

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 you first start taking antidepressants, since these medicines all take time to work.

You may be more likely to think like this:

- if you have previously had thoughts about killing yourself or harming yourself.
- if you are a young adult.

Studies have shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant. If you have thoughts of harming or killing yourself at any time, contact your health care provider or go to a hospital immediately. 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.

Children and adolescents

The safety of VENLOR XR TABLET has not been studied in children less than 18 years of age (see **Do not take VENLOR XR TABLET)**.

Symptoms such as having suicidal thoughts and thoughts of self-harm may be increased in children.

Other medicines and VENLOR XR TABLET

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

The following medicines may increase the effect of VENLOR XR TABLET:

- cimetidine (used to treat heartburn and stomach ulcers)
- ketoconazole, itraconazole, voriconazole, posaconazole (used to treat fungal infections)
- atazanavir, ritonavir, saquinavir, nelfinavir (used in the treatment of HIV/AIDS)
- clarithromycin (used in the treatment of bacterial infections)
- medicines that inhibit the CYP2D6 liver enzyme such as fluoxetine (used in the treatment of depression).

VENLOR XR TABLET may reduce the effect of the following medicines:

- indinavir (used in the treatment of HIV/AIDS).

VENLOR XR TABLET may increase the effect of the following medicines:

- haloperidol (used in the treatment of psychosis)
- desipramine (used in the treatment of depression)
- risperidone (used in the treatment of psychosis).

When VENLOR XR TABLET is used together with the following medicines, it may increase the risk of unwanted side effects:

- quinidine, amiodarone, dotalol, dofetilide (used to treat abnormal heart rhythm)
- thioridazine (used in the treatment of psychosis)
- erythromycin, moxifloxacin (used for bacterial infections)
- some antihistamines

- lithium (used to treat mood disorders)
- medicines that fall under the class of monoamine oxidase inhibitors (such as moclobemide).

VENLOR XR TABLET with food, drink, and alcohol

VENLOR XR TABLET should be swallowed whole with a glass of water and should be taken with food (see **section 3**).

Avoid alcohol while being treated with VENLOR XR TABLET.

Pregnancy, breastfeeding, and fertility

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 VENLOR XR TABLET.

If you take VENLOR XR TABLET 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 VENLOR XR TABLET so they can advise you.

Pregnancy

Do not take VENLOR XR TABLET if you are pregnant as it may affect your newborn (see **section 2**).

Breastfeeding

VENLOR XR TABLET passes into human milk and therefore should not be used by breastfeeding mothers (see **section 2**).

Fertility

The effect of VENLOR XR TABLET on fertility is not known.

Driving and using machines

VENLOR XR TABLET may affect your judgement, thinking and motor skills, as well as cause dizziness and unsteadiness (especially the elderly), which may impact your ability to drive and use machines. It is not always possible to predict to what extent VENLOR XR TABLET 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 VENLOR XR TABLET affects them.

VENLOR XR TABLET contains mannitol

VENLOR XR TABLET contains mannitol which may have a mild laxative effect.

VENLOR XR TABLET contains lactose monohydrate

VENLOR XR TABLET contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking VENLOR XR TABLET.

3. How to take VENLOR XR TABLET

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

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

The usual dose is 75 mg taken once daily. Your dose may be increased based on individual need. The maximum dose is 375 mg. The dose must be taken at approximately the same time each day, either in the morning or in the evening.

Patients with kidney or liver problems will be prescribed a lower dose by the doctor.

VENLOR XR TABLET should be taken with food, swallowed whole, with a glass of water. VENLOR XR TABLET should not be divided, crushed, chewed or dissolved. VENLOR XR TABLET keeps its shape during the whole digestion releasing the active ingredient (venlafaxine) and is passed out intact in the stool.

Your doctor will tell you how long your treatment with VENLOR XR TABLET will last. If you have the impression that the effect of VENLOR XR TABLET is too strong or too weak, tell your doctor or pharmacist.

If you take more VENLOR XR TABLET than you should

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

Overdose of VENLOR XR TABLET is common in combination with alcohol or other medicines. An overdose of VENLOR XR TABLET may result in increased side effects and even death.

If you forget to take VENLOR XR TABLET

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

4. Possible side effects

VENLOR XR TABLET can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- any heart related side effects such as chest pain.

These are all very serious side effects. If you have them, you may have had a serious reaction to VENLOR XR TABLET. 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:

- chest tightness, wheezing, trouble swallowing or breathing,
- life threatening irregular heartbeat, rapid or slow heartbeat,
- signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of co-ordination, fast heartbeat, palpitations, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting,
- unexplained muscle pain, tenderness or weakness, abnormal muscle breakdown which can lead to kidney problems,
- less urine than is normal for you,

- Stevens-Johnson syndrome or other serious skin disorders (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters),
- serious illness with blistering of the skin,
- abnormal bleeding of skin, eye, or stomach,
- thinking of killing yourself (suicidal ideation) and suicidal behaviour,
- having hallucinations (strange visions or sounds),
- high blood pressure or low blood pressure (feeling dizzy when standing up),
- seizures, convulsions (fits), shivering,
- inflammation of the liver (hepatitis), with symptoms such as fatigue, loss of appetite and muscle or joint ache,
- memory loss, impaired concentration,
- rise in pressure in your eyes.

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

Frequent side effects:

- increased cholesterol, loss of appetite, weight loss,
- abnormal dreams, nervousness, unable to sleep, lower sex drive, anxiety, agitation, feeling like you are observing yourself from outside your body,
- dizziness, increased muscle tonus, pins and needles, tremors, metallic taste sensation persists in the mouth, sedation,
- inability to change eye focus, dilated pupils, visual disturbances,
- ringing in the ears,
- irregular heartbeats you can feel, fast heartrate/pulse,
- high blood pressure, hot flushes,
- yawning,

- decreased appetite, constipation, nausea, vomiting, loss of appetite, (diarrhoea) frequent loose watery stools, which can cause dehydration and may require hospitalisation and treatment with intravenous fluids, gas, upset stomach, abdominal pain, dry mouth,
- joint pain, increased muscle tone/muscle stiffness, numbness/tingling in the hands or feet, muscle aches,
- inability to pass urine, difficulties passing urine, more frequent urination,
- abnormal ejaculation/orgasm (males), inability to achieve an orgasm, erectile dysfunction, sexual dysfunction,
- excessive sweating (including night sweats),
- weakness (asthenia), fatigue/tiredness, headache, pain, abdominal, chest and back pain, chills, fever,
- weight loss.

Less frequent side effects:

- weight gain,
- altered taste,
- blood tests showing low blood sodium levels,
- state of indifference – lack of feeling or emotion, hallucinations (seeing or hearing things which are not there), overactivity, racing thoughts and decreased need for sleep (mania), feeling overexcited or euphoric, losing touch with reality,
- involuntary movements of the muscles, fits/seizures, slurred speech, loss of consciousness, impaired co-ordination and balance,
- irregular heartbeat, low blood pressure when standing up from sitting down,

- grinding of the teeth, inflammation of the pancreas causing pain in the upper abdomen (pancreatitis), black tarry stools (faeces) or blood in stools, which can be a sign of internal bleeding,
- abnormal hair loss, bull's eye shaped lesions, hives, sensitivity to sunlight, bruising,
- abnormal liver function test results,
- loss of bladder control,
- difficulty in controlling movements, muscle spasm,
- abnormal orgasm (female), excessive or inappropriate production of milk, menstrual changes, abnormal menstrual cycle.

Side effects with unknown frequency:

- unexpected bleeding, e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins), reduction in blood platelets which increases risk of bleeding or bruising, blood disorders, prolonged bleeding,
- excessive water intake (known as SIADH), increased prolactin levels (symptoms may include irregular menstrual periods or no menstrual periods, milky discharge from the breasts when not pregnant or breastfeeding, acne and excessive body and facial hair growth),
- abnormal thinking, aggression, memory loss, depression, rapid changes in mood, thinking of committing suicide, delirium, confusion,
- uncontrollable movements of mouth, tongue and limbs, numbness, lockjaw,
- vertigo (feeling off balance),
- low blood pressure,
- sore throat, stuffy nose,

- increased appetite, indigestion, belching, flatulence,
- menstrual irregularities such as increased bleeding or increased irregular bleeding,
- heavy vaginal bleeding shortly after birth (post-partum haemorrhage), see **section 2** for more information.

Do not be concerned if you see a tablet in your stools after taking this medicine. As the tablet travels the length of your gastrointestinal tract, the active ingredient (venlafaxine) is slowly released. The shape of the tablet remains undissolved and is eliminated in your stools. Therefore, even though you may see a tablet in your stools, your dose of medicine has been absorbed.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of VENLOR XR TABLET.

5. How to store VENLOR XR TABLET

Store at or below 25 °C.

Store all medicines out of reach of children.

Store in the original container.

Do not use after the expiry date stated on the outer 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 VENLOR XR TABLET contains

The active substance in VENLOR XR TABLET is venlafaxine hydrochloride equivalent to venlafaxine 37,5 mg, 75 mg, 150 mg, 225 mg, or 300 mg.

The other ingredients are:

- Cellulose acetate 320S
- Cellulose acetate 398-10
- Macrogol 400
- Magnesium stearate
- Mannitol
- Microcrystalline cellulose
- Opadry® Y-30-18037 white
- Povidone K 90
- Silica colloidal anhydrous

Composition of the Opadry® Y-30-18037 white

- Hypromellose
- Lactose monohydrate
- Titanium dioxide
- Triacetin

What VENLOR XR TABLET looks like and contents of the pack

VENLOR XR 37,5 mg TABLET:	Round, biconvex, white to off white coloured tablets with a little pierce in one side.
VENLOR XR 75 mg TABLET:	Round, biconvex, white to off white coloured tablets with a little pierce in one side.
VENLOR XR 150 mg TABLET:	Round, biconvex, white to off white coloured tablets with a little pierce in one side.
VENLOR XR 225 mg TABLET:	Round, biconvex, white to off white coloured tablets with a little pierce in one side.
VENLOR XR 300 mg TABLET:	Round, biconvex, white to off white coloured tablets with a little pierce in one side.

VENLOR XR TABLET prolonged-release tablets are packaged in blisters composed of PVC-PCTFE/Aluminium.

VENLOR XR TABLET is packed in the following pack sizes:

VENLOR XR 37,5 mg TABLET, prolonged-release tablets:
PVC-Polychlorotrifluoroethylene/Aluminium Blister: 10, 14, 20, 28, 30, 50, 56, 60, 100 and 500 (only for hospital use) prolonged-release tablets.

VENLOR XR 75 mg TABLET, prolonged-release tablets:
PVC-PCTFE/Aluminium Blister: 10, 14, 20, 28, 30, 50, 56, 60, 70, 98, 100 and 500 (only for hospital use) prolonged-release tablets.

VENLOR XR 150 mg TABLET, prolonged-release tablets:

PVC-PCTFE/Aluminium Blister: 10, 14, 20, 28, 30, 50, 56, 60, 70, 98, 100 and 500 (only for hospital use) prolonged-release tablets.

VENLOR XR 225 mg TABLET, prolonged-release tablets:
PVC-PCTFE/Aluminium Blister: 10, 14, 20, 28, 30, 50, 56, 60, 70, 98, 100 and 500 (only for hospital use) prolonged-release tablets.

VENLOR XR 300 mg TABLET, prolonged-released tablets:
PVC-PCTFE/Aluminium Blister: 10, 14, 20, 28, 30, 50, 56, 60, 70, 98, 100 and 500 (only for hospital use) prolonged-release tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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VENLOR XR 37,5 mg TABLET: 56/1.2/0037

VENLOR XR 75 mg TABLET: 56/1.2/0038

VENLOR XR 150 mg TABLET: 56/1.2/0039

VENLOR XR 225 mg TABLET: 56/1.2/0035

VENLOR XR 300 mg TABLET: 56/1.2/0036

Access to the corresponding Professional Information

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER:
The QR Code to be generated and included after approval.