PROPOSED PATIENT INFORMATION LEAFLET FOR

VENLOR XR 37,5

VENLOR XR 75

VENLOR XR 150

SCHEDULING STATUS: S5

VENLOR XR 37,5; 37,5 mg, extended-release capsules

VENLOR XR 75; 75 mg, extended-release capsules

VENLOR XR 150; 150 mg, extended-release capsules

Venlafaxine hydrochloride equivalent to venlafaxine.

Contains sugar: sucrose.

VENLOR XR 37,5: sucrose 50,61 mg per capsule.

VENLOR XR 75: sucrose 101,21 mg per capsule.

VENLOR XR 150: sucrose 202,42 mg per capsule.

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

- 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 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 is and what it is used for

VENLOR XR contains the active ingredient called venlafaxine hydrochloride. VENLOR XR is an antidepressant that belongs to a group of medicines called Serotonin and Noradrenaline Reuptake Inhibitors (SNRIs). This class of medicines is used to treat depression and other conditions such as anxiety disorders.

VENLOR XR is a treatment for adults with depression. It is also a treatment for adults with the following anxiety disorders: generalised anxiety disorder and social anxiety disorder (fear or avoidance of social situation). VENLOR XR is also used to prevent relapse.

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

Do not take VENLOR XR:

- if you are hypersensitive (allergic) to venlafaxine or any of the other ingredients of VENLOR XR (listed in **section 6**).
- if you are under the age of 18 years.
- if you are pregnant or breastfeeding your baby (see **Pregnancy, breastfeeding, and fertility**).
- if you are also taking, or have taken within the last 14 days, any medicines known as monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease. Taking an MAOI together with VENLOR XR, can cause serious or even life-threatening side effects like tremor, convulsions, agitation, and increased body

temperature (hyperthermia) due to the risk of serotonin syndrome. Also, you must wait at least seven days after you stop taking VENLOR XR before you take any MAOI (see **Other medicines and VENLOR XR**).

Warnings and precautions

Before you start treatment with VENLOR XR, tell your doctor if any of the following applies to you as you may then require a lower dose or special precautions:

- if you have raised pressure in your eye (glaucoma).
- if you have a history of high blood pressure.
- if you have a history of heart problems or an abnormal heart rhythm.
- if you have a history of seizures (convulsions / fits) or epilepsy.
- if you have a tendency to bleed easily (history of bleeding disorders) or if you develop bruises easily, or if you are taking other medicines that may increase the risk of bleeding e.g., warfarin (used to prevent blood clots) or if you are pregnant (see **Pregnancy, breastfeeding and fertility**).
- if you have a history of high cholesterol.
- if you are taking any weight loss agents.
- if you have a history of, or if someone in your family has had mania or bipolar disorder (feeling over-excited or euphoric).
- if you have a history of aggressive behaviour.
- if you have been diagnosed with impaired liver function.
- you have kidney disease.
- diabetes mellitus.

Please inform your doctor if you have attempted suicide in the past or if you frequently think about suicide or death. When you start treatment with VENLOR XR these thoughts may persist for some time, and it may take several weeks before you experience relief. If you frequently think about suicide or harming yourself or if you feel that everything is

becoming too much and that it may be better if you die, please inform your doctor as a matter of urgency.

If you take other medicines know as monoamine oxidase inhibitors (see **Do not take VENLOR XR**) or other medicines that increase serotonin levels, you may develop a condition known as the serotonin syndrome. Symptoms of this syndrome include confusion, seeing or hearing things that are not real (hallucinations), agitation, hyperactivity, shivering, fever, tremors, fast heartbeat, eye movements, severe muscle spasms, incoordination of movements, and abnormal behaviour (see **Possible side effects**). Please report any of these symptoms to your doctor as a matter of urgency.

VENLOR XR may lower your blood levels of sodium (hyponatraemia). The likelihood of this is greater in elderly patients or patients taking diuretics ('water tablets'). Please inform your doctor if you develop nausea and vomiting, headache, confusion, loss of energy, fatigue, muscle weakness, muscle spasm or muscle cramps (see **Possible side effects**).

Do not stop taking VENLOR XR without your doctor's guidance as to how to gradually decrease the dose (see **If you stop taking VENLOR XR**).

Treatment with VENLOR XR may cause a condition known as akathisia (an unpleasant or distressing restlessness and a need to move often, or an inability to sit or stand still) during the first few weeks of treatment (see **Possible side effects**). Tell your doctor if this happens to you.

VENLOR XR may cause a rash, hives, or allergic reaction; notify your doctor if a rash appears.

VENLOR XR may cause a dry mouth, this may increase the risk of tooth decay. Therefore, take special care in your dental hygiene.

Treatment with VENLOR XR may interfere with laboratory tests used in the diagnosis of presence of certain medicines and cause false positive results.

Children and adolescents

Safety and efficacy of VENLOR XR in children under 18 years of age has not been established (see **Do not take VENLOR XR**). There have been increased reports of suicide attempt, suicidal thoughts, and hostility (predominantly aggression, oppositional behaviour and anger). Please report any such thoughts or behaviour to your doctor as soon as possible.

Other medicines and VENLOR XR

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

Please inform your doctor if you are taking any of the following medicines, as you may require a reduction in dose or special precautions:

- Monoamine oxidase inhibitors for the treatment of depression or Parkinson's disease must not be taken with VENLOR XR. You should wait 14 days after stopping a monoamine oxidase inhibitor before you start VENLOR XR and at least 7 days should elapse after you stop VENLOR XR before you can start treatment with a monoamine oxidase inhibitor (see **Do not take VENLOR XR** and **Warnings and precautions**).

- Serotonin syndrome, a potentially life-threatening condition, may occur when VENLOR XR is used with the following medications (see **Warnings and precautions**):
    - Triptans (used for migraine).
    - Other medicines to treat depression, for instance SNRIs (desvenlafaxine, duloxetine, levomilnacipran, milnacipran and tofenacin), SSRIs (Citalopram, escitalopram, paroxetine, fluoxetine, fluvoxamine, and sertraline), tricyclics (amitriptyline, clomipramine and imipramine) or medicines containing lithium.
    - Medicines containing moclobemide, a MAOI (used to treat depression).
    - Linezolid, an antibiotic.
    - Medicines containing sibutramine (used for weight loss).
    - Medicines containing tramadol, fentanyl, tapentadol, pethidine, or pentazocine (use to treat severe pain).
    - Medicines containing dextromethorphan (used to treat coughing).
    - Medicines containing methadone (used to treat opioid drug addiction or severe pain).
    - Medicines containing methylene blue (used to treat high levels of methaemoglobin in the blood).
    - Products containing St. John's Wort (also called *Hypericum perforatum*, a natural or herbal remedy used to treat mild depression).
    - Products containing tryptophan (used for problems such as sleep and depression).
    - Antipsychotic or other dopamine antagonist, e.g. chlorpromazine haloperidol, metoclopramide, quetiapine, risperidone and sulpiride.

Signs and symptoms of serotonin syndrome may include a combination of the following: restlessness, seeing or hearing things that are not real (hallucinations), loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting.

In the most severe form, serotonin syndrome can resemble Neuroleptic Malignant Syndrome (NMS). Signs and symptoms of NMS may include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).

Tell your doctor immediately or go to the casualty department at your nearest hospital if you think you are experiencing serotonin syndrome.

- Tell your doctor if you are taking medicines that can affect your heart rhythm, examples of these medicines include:
    - Antiarrhythmics such as quinidine, amiodarone, sotalol or dofetilide (used to treat abnormal heart rhythm).
    - Antipsychotics such as thioridazine.
    - Antibiotics such as erythromycin or moxifloxacin (used to treat bacterial infections).
    - Antihistamines (used to treat allergy).
- Ketoconazole, itraconazole, voriconazole and posaconazole (an antifungal medicine).
- Haloperidol or risperidone (to treat psychiatric conditions).
- Metoprolol (a beta blocker to treat high blood pressure and heart problems).
- Warfarin (a blood thinner).
- Lithium for the treatment of psychosis or manic depression (bipolar disorder).
- Cimetidine used for the treatment of stomach ulcers, heartburn, or acid reflux.
- Diazepam used for the treatment of anxiety.

- Indinavir, atazanavir, nelfinavir, saquinavir, ritonavir used for the treatment of HIV/AIDS.
- Alcohol.
- Imipramine, used for depression.
- Clarithromycin, telithromycin (antibiotics).

VENLOR XR with food, drink, and alcohol

VENLOR XR should be swallowed whole with a glass of water and should be taken with food. The capsule may not be chewed, crushed, divided, or dissolved.

You should avoid alcohol while you are taking VENLOR XR.

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.

Do not take VENLOR XR while you are pregnant or breastfeeding your baby (see **Do not take VENLOR XR**). The safe and effective use of VENLOR XR in pregnancy and while you are breastfeeding your baby has not been established. VENLOR XR is excreted in breast milk.

If you take VENLOR XR 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 so they can advise you.

The effect of VENLOR XR on fertility is not known.

Driving and using machines

There is likelihood that VENLOR XR will impair your ability to drive or use machines. Do not drive or operate machinery until you know how VENLOR XR affects you.

Do not take VENLOR XR with alcohol, as your ability to drive or operate machinery may be impaired.

VENLOR XR contains sucrose

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

VENLOR XR contains sunset yellow

VENLOR XR contains sunset yellow which may cause allergic reactions.

VENLOR XR contains Ponceau 4R

VENLOR XR contains Ponceau 4R which may cause allergic reactions.

3. How to take VENLOR XR

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

Always take VENLOR XR exactly as your doctor or pharmacist has told you.

You should check with your doctor or pharmacist if you are not sure.

Depending on your diagnosis and your individual response to treatment, your doctor will decide on the dosage of VENLOR XR and how long treatment will last. The usual recommended starting dose for treatment of depression, generalised anxiety disorder and social anxiety disorder is 75 mg per day. The dose can be gradually raised by your doctor

if needed. The maximum dose for generalised anxiety disorder, and social anxiety disorder is 225 mg per day. The maximum dose for depression is 375 mg per day.

VENLOR XR must be taken with food at approximately the same time each day, either in the morning or in the evening. Capsules must be swallowed whole with fluid and not opened, crushed, chewed, or dissolved.

If you have liver or kidney problems, talk to your doctor, since your dose of VENLOR XR may need to be adjusted.

Do not stop taking VENLOR XR without talking to your doctor. When stopping VENLOR XR therapy, the doctor will decrease your dose gradually to prevent discontinuation/withdrawal symptoms developing (see **If you stop taking VENLOR XR**).

If you have the impression that the effect of VENLOR XR is too strong or too weak, please discuss this with your doctor or pharmacist.

If you take more VENLOR XR than you should

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience blurred vision, nausea and vomiting, convulsions or seizures, fast or slow heartbeat, changes in your level of consciousness ranging from dizziness and sleepiness to coma, dizziness when standing, feeling that you or your environment is spinning, changes to your heart rhythm and death. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take VENLOR XR

Always take VENLOR XR as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking VENLOR XR

After using VENLOR XR for a long period, abruptly stopping your treatment may cause withdrawal symptoms. VENLOR XR withdrawal symptoms may include dizziness, pins and needles, sleeplessness and intense dreams, agitation, anxiety, nausea and vomiting, tremor, headache, inappropriate behaviour (hypomania), nervousness, confusion, sleepiness or drowsiness, convulsion, feeling that you and your environment is spinning, flu-like symptoms, ringing in ears, impaired coordination and balance, sweating, dry mouth, loss of appetite and diarrhoea (loose stool). Generally, these symptoms are self-limiting; however, in some patients they may be severe and/or prolonged. Always follow your doctor's instructions carefully when treatment with VENLOR XR is stopped. Do NOT stop treatment without your doctor's consent.

4. Possible side effects

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

After using VENLOR XR for a long period, abruptly stopping your treatment may cause withdrawal symptoms (see **If you stop taking VENLOR XR**).

If any of the following happens, stop taking VENLOR XR and tell your doctor immediately

or go to the casualty department at your nearest hospital:

- allergic reactions, presenting with swelling of the lips, tongue or face, hives, itching, wheezing or laboured breathing (anaphylaxis / angioedema),
- those that occur less frequently:
    - fainting,
    - chest pain,
- those for which the frequency is not known:
    - chest tightness, wheezing, trouble swallowing or breathing,
    - severe rash, itching or hives (elevated patches of red or pale skin that often itch), any skin rash with blister formation,
    - signs and symptoms of serotonin syndrome which may include restlessness, seeing or hearing things that are not real (hallucinations), loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting. In the most severe form, serotonin syndrome can resemble Neuroleptic Malignant Syndrome (NMS). Signs and symptoms of NMS may include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test),
    - bruising of the skin, unusual bleeding pinpoint red spots on the skin, bleeding from gums, shortness of breath upon exertion, unusual tiredness or weakness, fever, and chills, all the above symptoms may be due to abnormal blood cells and platelet count.

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

- Those that occur frequently:
    - heart problems, such as a fast or irregular heart rate,
    - increased blood pressure,
    - sudden reddening of skin and warm feeling,
    - signs of recurrent infections such as fever or a sore throat,
    - coughing, shortness of breath and a high temperature,
    - eye problems such as blurred vision or dilated pupils,
    - psychiatric problems, such as hyperactivity and euphoria (feeling unusually overexcited),
    - less urine than is normal for you, urinary hesitation or increase in the frequency of urinating, pain over the kidney area, discoloration of urine as this may be due to kidney damage,
    - pins and needles.
- Those that occur less frequently:
    - black (tarry) stools or blood in stools,
    - nerve problems, such as movement disorder, seizures or fits, unpleasant or distressing restlessness,
    - inability to sit still and restlessness.
- Those for which the frequency is not known:
    - yellow skin or eyes, itchiness or dark urine accompanied by loss of appetite, pain over the liver area, fever and nausea, which may be symptoms of inflammation of the liver (hepatitis) or pancreas,
    - suicidal ideation, and suicidal behaviour,
    - heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see **Pregnancy, breastfeeding, and fertility** for more information.

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:

- nausea and vomiting,
- stomach cramps or stomach pains,
- diarrhoea,
- constipation,
- loss of appetite,
- dry mouth,
- burping, gas and indigestion,
- distortion of sense of taste,
- headache, dizziness, tremor (shakiness), increased muscle tension,
- sleeplessness,
- sleepiness or drowsiness,
- abnormal dreams,
- confusion, nervousness, feeling as though your thoughts and actions are not your own or ‘unreal’ (depersonalisation), anxiety, depression,
- self-awareness,
- loss of memory,
- abnormal thinking,
- abnormal ejaculation or orgasm,
- decreased libido,
- inability to achieve orgasm,
- menstrual disorders (increased or irregular bleeding),
- erectile dysfunction,

- increase sweating, including night sweats, hair loss, skin rash on areas exposed to the sun,
- weakness or a lack of energy and tiredness,
- joint pain, muscle pain, neck pain, back pain,
- increased blood cholesterol levels,
- ringing in the ears,
- eye problems such as blurred vision or dilated pupils,
- yawning and runny nose.

Less frequent side effects:

- hyponatraemia (condition where the level of sodium in your blood is low). Nausea, vomiting, headache, confusion, loss of energy, muscle cramps/spasms, muscle weakness since the combination of these symptoms may be due to low blood sodium levels,
- lack of interest, lack of enthusiasm or concern,
- seeing or hearing things that are not real (hallucinations), agitation, extremely elevated mood with inappropriate behaviour (mania), derealisation (unreal),
- grinding of teeth and clenching of jaw,
- thoughts about suicide,
- abnormal coordination or balance,
- feeling dizzy when you stand up, swelling of your ankles or lower legs,
- jerking of muscle group,
- migraine,
- photosensitivity reactions,
- rash, hives, and itching,
- increased appetite, and increase or decrease of weight,

- loss of bladder control.

Side effects with unknown frequency:

- hostility (aggression, oppositional behaviour, anger),
- increased pressure in the eye (glaucoma), eye pain,
- feeling that you or your environment is spinning,
- low blood pressure.

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) found on SAHPRA website or to Cipla Medpro (Pty) Ltd. by e-mail: 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.

5. How to store VENLOR XR

Store at or below 25 °C.

Store all medicines out of reach of children.

Keep blister strips in outer carton until required for use.

Do not use after the expiry date stated on the container.

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 contains

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

The other ingredients are:

- Sugar Spheres
- Hydroxy propyl cellulose
- Isopropyl alcohol
- Purified water

Composition of the seal coating

- Hydroxy propyl methyl cellulose
- Purified talc
- Isopropyl alcohol
- Purified water

Blending

- Purified talc
- EHG capsule shell

Composition of the sustained release coating

- Hydroxy propyl methyl cellulose (E-15)
- Ethyl cellulose aqueous dispersion Type B
- Purified water

Composition of Surelease E-7-19030 clear

- Ammonium hydroxide 28%
- Colloidal anhydrous silica
- Dibutyl sebacate
- Ethyl cellulose 20 cp
- Oleic acid
- Purified water

Composition of Hard Gelatin Capsule Shell

VENLOR XR 37,5 mg:

- Hard gelatin capsule body(clear)
    - Sodium lauryl sulphate
    - Gelatin
- Hard gelatin capsule cap(orange)
    - Ponceau 4R
    - Quinoline yellow
    - Titanium dioxide
    - Sodium lauryl sulphate
    - Gelatin

VENLOR XR 75 mg:

- Hard gelatin capsule body(clear)
    - Sodium lauryl sulphate
    - Gelatin
- Hard gelatin capsule cap(yellow)
    - Sunset yellow

- Quinoline yellow
- Titanium dioxide
- Sodium lauryl sulphate
- Gelatin

VENLOR XR 150 mg:

- Hard gelatin capsule body(clear)
  - Sodium lauryl sulphate
  - Gelatin
- Hard gelatin capsule cap(yellow)
  - Sunset yellow
  - Quinoline yellow
  - Patent Blue
  - Titanium dioxide
  - Sodium lauryl sulphate
  - Gelatin

What VENLOR XR looks like and contents of the pack

VENLOR XR 37,5: White to off-white pellets filled in hard gelatin capsule shells “size 3” with orange cap and clear transparent body.

VENLOR XR 75: White to off-white pellets filled in hard gelatin capsule shells “size 1” with yellow cap and clear transparent body.

VENLOR XR 150: White to off-white pellets filled in hard gelatin capsule shells “size 0” with buff cap and clear transparent body.

VENLOR XR is packed in:

VENLOR XR 37,5: PVC film/aluminium foil blister strips of 10 capsules, packed in 30’s.

VENLOR XR 75: PVC film/aluminium foil blister strips of 10 capsules, packed in 30's.

VENLOR XR 150: PVC film/aluminium foil blister strips of 10 capsules, packed in 30's.

Not all pack sizes may be marketed.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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Registration number(s)

VENLOR XR 37,5: A40/1.2/0032

VENLOR XR 75: A40/1.2/0033

VENLOR XR 150: A40/1.2/0034

VENLOR XR 37,5

Botswana: S2 BOT1302381

Namibia: NS2 06/1.2/0299

VENLOR XR 75

Botswana: S2 BOT0801423

Namibia: NS2 06/1.2/0300

VENLOR XR 150

Botswana: S2 BOT0801424

Namibia: NS2 06/1.2/0301

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

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