**PATIENT INFORMATION LEAFLET**

**ILLOVEX XR RANGE**

**SCHEDULING STATUS:**

S5

**ILLOVEX XR 37,5 mg** extended release film coated tablets

**ILLOVEX XR 75 mg** extended release film coated tablets

**ILLOVEX XR 150 mg** extended release film coated tablets

**ILLOVEX XR 225 mg** extended release film coated tablets

**ILLOVEX XR 300 mg** extended release film coated tablets

Venlafaxine hydrochloride

Contains sugar, lactose monohydrate (37,5 mg - 3,2 mg; 75 mg – 3,6 mg; 150 mg – 6,0 mg; 225 mg – 6,8 mg, 300 mg – 9,2 mg) and mannitol (37,5 mg – 5 mg; 75 mg – 10 mg; 150 mg – 20 mg; 225 mg – 30 mg, 300 mg – 40 mg)

**Read all of this leaflet carefully before you start taking ILLOVEX XR**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ILLOVEX 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 ILLOVEX XR is and what it is used for
2. What you need to know before you take ILLOVEX XR
3. How to take ILLOVEX XR

4. Possible side effects
5. How to store ILLOVEX XR
6. Contents of the pack and other information

## 1. What ILLOVEX XR is and what it is used for

ILLOVEX XR contains venlafaxine, it is an antidepressant that belongs to a group of medicines called Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs). This group of medicines is used to treat depression and other conditions such as anxiety disorders. It is thought that people who are depressed and/or anxious have lower levels of serotonin and noradrenaline in the brain. It is not fully understood how antidepressants work, but they may help by increasing the levels of serotonin and noradrenaline in the brain.

ILLOVEX XR is used:

- in the treatment of depression (which includes anxiety associated with depression), severe and persistent anxiety known as Generalised Anxiety Disorder (GAD), social anxiety disorder (also known as social phobia).
- for prevention of recurrence of major depressive episodes.

## 2. What you need to know before you take ILLOVEX XR

Do not take ILLOVEX XR:

- if you are hypersensitive (allergic) to venlafaxine or any of the other ingredients of ILLOVEX XR (see section 6)

- if you are taking, or have taken within the last 14 days, medicines known as Monoamine Oxidase Inhibitors (MAOIs) used to treat depression or Parkinson's disease. Taking an MAOI together with ILLOVEX XR can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking ILLOVEX XR before you take any MAOI (see Other medicines with ILLOVEX XR specifically the section about Serotonin Syndrome)
- if you have high blood pressure which is not being treated with medicine
- if you have been told by your doctor that you have a high risk of serious abnormal rapid heartbeats
- if you suffer from epilepsy
- children under the age of 18 years of age (see Take special care with ILLOVEX XR)
- if you are pregnant or breastfeeding (see Pregnancy and breastfeeding).

**Warnings and precautions**

Take special care and talk to your doctor before taking ILLOVEX XR:

- if your depression worsens
- if you take other medicines which, when taken with ILLOVEX XR, could increase the risk of developing serotonin syndrome
- if you have eye problems, such as certain types of glaucoma (increased pressure in the eye)
- if you have a history of heart problems as ILLOVEX XR may increase your heart rate
- if you have a history of high blood pressure as ILLOVEX XR may increase blood pressure levels
- if you have a history of epilepsy or fits (seizures) as ILLOVEX XR may increase seizure frequency
- if you or anyone in your family has a history of mania or bipolar disorder (feeling over-excited or euphoric)
- if you have a history of aggressive behaviour as episodes of aggression may increase

- if you are taking water tablets or you have recently lost a lot of body fluids due to vomiting or diarrhoea or are elderly
- if you have a tendency to bruise or bleed easily, or you are taking medicines that may increase the risk of bleeding (e.g. warfarin used to thin the blood in the prevention of blood clots) and if you are due to have surgery as ILLOVEX XR increases the risk of blood loss during surgery
- if you are pregnant and your doctor has prescribed ILLOVEX XR for you in the month before your baby is due, there is a risk of excessive bleeding after childbirth
- if you develop a hives or a skin rash related to an allergic reaction during treatment
- if you are taking weight loss medicine. Taking ILLOVEX XR and weight loss medicine at the same time is not recommended
- if you have high cholesterol, monitoring these levels closely is recommended during treatment with ILLOVEX XR
- if you have liver or kidney problems as your dose of ILLOVEX XR may need to be adjusted
- if you are stopping the treatment with ILLOVEX XR, it should be done gradually, and you should be monitored by your healthcare 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.
- if you take ILLOVEX XR you might develop a condition of feeling restless and the inability to stay still especially in the first few weeks of treatment

- if you take ILLOVEX XR you might develop a dry mouth and have a higher risk tooth decay. Good dental hygiene is advised
- if you have diabetes
- if you are taking ILLOVEX XR it might be possible that you will have false-positive urine screening tests for phencyclidine (PCP) and amphetamine.

**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 healthcare professional 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:**

ILLOVEX XR should 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 this class of medicine. The long-term safety effects concerning growth, maturation, intellectual and behavioural development of this medicine in this age group, has not yet been demonstrated.

**Other medicines and ILLOVEX XR**

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

Some of the medicines that may interact with ILLOVEX XR are:

- Monoamine Oxidase Inhibitors which are used to treat depression or Parkinson's disease must not be taken with ILLOVEX XR. e.g. phenelzine, moclobemide (see Do not take ILLOVEX XR).
- medicine that works on the central nervous system e.g. benzodiazepines like diazepam (used to treat anxiety, alcohol withdrawal and seizures) and alprazolam (used to treat anxiety and panic disorders); barbiturates like mephobarbital (used to treat anxiety, tension and sleep disorders); stimulants like methylphenidate and dextroamphetamine (used to treat attention deficit disorder (ADHD)).
- certain medicine in combination with ILLOVEX XR can cause the development of a condition known as serotonin syndrome, a potentially life-threatening condition which could affect your behaviour or state of mental health, cause changes to your blood pressure, heart rate or sweating, or lead to stomach or muscle problems.

  Examples of these medicines include:

  - other medicines to treat depression or mental health problems, for instance medicines containing lithium, SSRIs, other SNRIs,
  - sibutramine (for weight loss),
  - tramadol (to relieve pain),
  - triptans (to treat migraine),

- products containing St. John's Wort (also called Hypericum perforatum, a natural or herbal remedy used to treat mild depression)
- medicines containing linezolid (to treat infections)
- products containing tryptophan (used for problems such as sleep and depression)

The following medicines may also interact with ILLOVEX XR.

- metoclopramide (to treat nausea and vomiting)
- antidysrhythmics such as propafenone (to treat abnormal heart rhythm)
- indinavir (antiviral treatment in HIV patients)

The following medicines may also interact with ILLOVEX XR and should be used with caution. It is especially important to mention to your healthcare professional or pharmacist if you are taking medicines containing:

- the antibacterial medicine co-amoxiclav (to treat infections)
- antipsychotics e.g. chlorpromazine (used to treat a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, unclear reasoning and becoming withdrawn)
- medicine like warfarin (to thin blood and prevent blood clots)
- haloperidol or risperidone (to treat psychiatric conditions)
- cimetidine (a medicine used to treat heartburn and stomach ulcers) may increase the effect of ILLOVEX XR
- the antidepressant imipramine
- ketoconazole (to treat fungal infections)
- metoprolol (to treat high blood pressure and heart problems).

- erythromycin and clarithromycin (to treat infection), grapefruit, goldenseal), bupropion, (to treat depression) and amiodarone (to treat irregular heartbeat), may increase the effect of ILLOVEX XR

**ILLOVEX XR with food, drink and alcohol**

ILLOVEX XR should be taken with food, at approximately the same time each day, either in the morning or evening.

Avoid the consumption of alcohol whilst taking ILLOVEX XR.

**Pregnancy and breastfeeding**

Do not take ILLOVEX XR if you are pregnant, planning to become pregnant or think you may be pregnant. If you become pregnant, please contact your healthcare professional or healthcare provider immediately.

If you take ILLOVEX 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 ILLOVEX XR so they can advise you.

Do not take ILLOVEX XR if you are breastfeeding your baby as the active ingredients in ILLOVEX XR may appear in breast milk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using ILLOVEX XR.

**Driving and using machines**

ILLOVEX XR may affect your judgement, cause you not to think clearly, affect your body movements, cause dizziness and unsteadiness (especially the elderly). Make sure you know how you react to

ILLOVEX XR before driving a vehicle, operating machinery, or do anything else that could be dangerous.

**ILLOVEX XR contains lactose and mannitol**

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

ILLOVEX XR may have a mild laxative effect.

**3. How to take ILLOVEX XR**

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

Always use ILLOVEX XR exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose for ILLOVEX XR is 75 mg (given as either 1 x 75 mg tablet or 2 x 37,5 mg tablets) once a day. The dose can be increased gradually by your doctor, to a maximum of 225 mg ILLOVEX XR taken once daily if required. If you are being treated for depression, the dose may be increased up to 375 mg daily.

ILLOVEX XR tablets should be taken with food, swallowed whole, with a glass of water. ILLOVEX XR should not be divided, crushed, chewed or dissolved.

Take ILLOVEX XR once a day, every day, at about the same time each day, after food.

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

Your doctor will tell you how long your treatment with ILLOVEX XR will last. Do not stop treatment early because unwanted side effects may occur.

If you have the impression that the effect of ILLOVEX XR is too strong or too weak, tell your doctor or pharmacist.

**If you take more ILLOVEX XR 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.

Overdose of ILLOVEX XR, mainly in combination with alcohol and/or other medicines can occur.

Symptoms of overdose may include:

- drowsy/sleepy to unconscious
- convulsions (seizures or fits)
- dilated pupils
- fast or slow heart rate/pulse
- vomiting
- electrocardiographic changes
- low blood pressure
- a feeling of losing balance, dizziness
- death.

**If you forget to take ILLOVEX XR:**

If you forget to take ILLOVEX XR, take a dose as soon as you remember, then continue to take ILLOVEX XR at the usual times. Do not take a double dose to make up for a forgotten dose.

**If you stop using ILLOVEX XR**

Do not stop taking your treatment or reduce the dose without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need ILLOVEX XR, he/she may ask you to reduce your dose slowly before stopping treatment altogether.

Side effects are known to occur when people stop using this medicine, especially when it is stopped suddenly, or the dose is reduced too quickly. Side effects experienced when stopping treatment are generally mild and will resolve without further treatment. The most common side effects may include elation and hyperactivity, anxiety, agitation, nervousness, inability to sleep and other sleeping problems, tiredness, sleepiness, tingling or numbness in hands or feet, dizziness, fits and seizures, a feeling of losing balance, headache, flu-like symptoms, ringing in the ears, impaired co-ordination and balance, shiver, 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.

**4. Possible side effects**

ILLOVEX XR can have side effects.

Not all side effects reported for ILLOVEX XR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using ILLOVEX XR, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop using ILLOVEX XR 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 or itching

- fainting

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

- 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 disorder (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.

Tell your doctor if you notice any of the following:

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
- 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, frequent loose watery stools (diarrhoea), 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 gain or loss.

Less frequent side effects:

- 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.

The following side effects have been reported but the frequency for them to occur is not known:

- 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
- abnormal thinking, aggression, memory loss, depression, rapid changes in mood, thinking of committing suicide
- 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 (postpartum haemorrhage), see section 2 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. 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 Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ILLOVEX XR.

## 5. How to store ILLOVEX XR

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the 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 ILLOVEX XR contains

The active substance is venlafaxine.

ILLOVEX XR 37,5 mg: Each extended release film coated tablet contains venlafaxine hydrochloride equivalent to 37,5 mg venlafaxine.

ILLOVEX XR 75 mg: Each extended release film coated tablet contains venlafaxine hydrochloride equivalent to 75 mg venlafaxine.

ILLOVEX XR 150 mg: Each extended release film coated tablet contains venlafaxine hydrochloride equivalent to 150 mg venlafaxine.

ILLOVEX XR 225 mg: Each extended release film coated tablet contains venlafaxine hydrochloride equivalent to 225 mg venlafaxine.

ILLOVEX XR 300 mg: Each extended release film coated tablet contains venlafaxine hydrochloride equivalent to 300 mg venlafaxine.

### The other ingredients are:

Cellulose acetate, hypromellose, lactose monohydrate, macrogol, magnesium stearate, mannitol, microcrystalline cellulose, povidone, silica colloidal anhydrous, titanium dioxide, triacetin.

### What ILLOVEX XR looks like and contents of the pack

ILLOVEX XR 37,5 mg: Round, biconvex, white, extended release film coated tablets, with a core diameter of 7 mm and core thickness of 4,2 mm.

ILLOVEX XR 75 mg: Round, biconvex, white, extended release film coated tablets, with a core diameter of 7,5 mm and core thickness of 4,2 mm.

ILLOVEX XR 150 mg: Round, biconvex, white, extended release film coated tablets, with a core diameter of 9,5 mm and core thickness of 5,1 mm.

ILLOVEX XR 225 mg: Round, biconvex, white, extended release film coated tablets, with a core diameter of 11 mm and core thickness of 6,2 mm.

ILLOVEX XR 300 mg: Round, biconvex, white, extended release film coated tablets, with a core diameter of 12,5 mm and a core thickness of 6,1 mm.

30's pack: Each cardboard carton encloses 3 x transparent PVC-PCTFE/Aluminium blisters strips containing 10 tablets each.

**Holder of Certificate of Registration**

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

**This leaflet was last revised in**

3 September 2021

**Registration numbers**

ILLOVEX XR 37,5 mg: A48/1.2/0910

**PATIENT INFORMATION LEAFLET**

**ILLOVEX XR RANGE**

ILLOVEX XR 75 mg: A48/1.2/0911

ILLOVEX XR 150 mg: A48/1.2/0912

ILLOVEX XR 225 mg: A48/1.2/0913

ILLOVEX XR 300 mg: A53/1.2/0467