PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

ODIVEN XR 37,5 capsules

ODIVEN XR 75 capsules

ODIVEN XR 150 capsules

Venlafaxine (as venlafaxine hydrochloride)

Sugar free

Read all of this leaflet carefully before you start taking ODIVEN XR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other health care provider.
- ODIVEN 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 ODIVEN XR is and what it is used for

ODIVEN XR is an antidepressant that belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). ODIVEN XR is an antidepressant used for the treatment of depression.

ODIVEN XR is also used for the treatment of the following anxiety disorders: generalised anxiety

disorder, social anxiety disorder (fear or avoidance of social situations) and panic disorder (panic attacks).

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

Do not take ODIVEN XR:

- If you are hypersensitive (allergic) to venlafaxine, or any of the other ingredients of ODIVEN XR (see section 6, What ODIVEN XR contains).
- If you are taking, or have taken within the last 14 days, an antidepressant that forms part of the class of irreversible monoamine oxidases inhibitors (MAOIs).
- You should wait 7 days after you have stopped taking ODIVEN XR before you start treatment with an irreversible MAOI.
- If you or your child is under 18 years of age.
- Pregnancy and breastfeeding.

Warnings and precautions

Take special care with ODIVEN XR:

Talk to your doctor or pharmacist before taking ODIVEN XR if you have any of the following conditions (this will help to decide if ODIVEN XR tablets are suitable for you):

- If you have thoughts about killing or harming yourself; contact your doctor or go to a hospital immediately.
- If you have a history of, or if someone in your family has had, mania or bipolar disorder (feeling overexcited or euphoric).
- If you experience symptoms such as agitation, hallucinations, incoordination, nausea, vomiting or diarrhoea while taking OVIDEN XR, contact your doctor immediately.
- If you have eye problems, such as glaucoma (increased pressure in the eye).
- If you have a history of high blood pressure (hypertension).
- If you recently had a heart attack or have any heart problems.
- If you have a history of fits (seizures).

- If you have a history of low sodium levels in your blood (hyponatraemia).
- If you have a tendency to develop bruises or bleed easily (history of bleeding disorders), or if you are taking other medicines that may increase the risk of bleeding, e.g. warfarin (used to prevent blood clots).
- If you have high cholesterol (fat) levels in your blood.
- If you are taking medicines for weight loss.
- If you have a history of aggressive behaviour.
- If you feel restless and feel like you cannot keep still, feel “high” or very overexcited, have jerky muscle movements which you cannot control.
- If you experience a dry mouth, as this may increase the risk of tooth decay (caries). You should therefore take special care of your dental hygiene.
- If you are diabetic, your blood glucose levels may be altered due to ODIVEN XR. Your doctor may need to adjust the dosage of your diabetes medicines.
- When going for screening/blood tests, remember to inform your doctor or health care professional that you are taking ODIVEN XR, as it may give false-positive results for other medicines.
- ODIVEN XR may cause symptoms of sexual dysfunction.

Children and adolescents

Do not give ODIVEN XR to children and adolescents under the age of 18 years because of the increased risk of side effects, such as suicide attempt, suicidal thoughts and hostility (anger, hatred and unfriendliness).

Other medicines and ODIVEN XR

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

Tell your doctor if you are taking any of the following medicines:

- Antidepressant medicines (used to treat depression).
- Triptans (used to treat migraine).
- Sibutramine (used for weight loss).
- St John's wort (a herbal medicine used to treat mild depression).
- Tramadol, fentanyl, tapentadol, pethidine or pentazocine (used to treat severe pain).
- Dextromethorphan (used to treat coughing).
- Methadone (used to treat drug addiction or severe pain).
- Tryptophan (used for sleeping).
- Antipsychotics (used to treat psychosis, a severe mental condition).
- Antidysrhythmic medicines (used to treat heart rhythm disorders).
- Antibiotics (including macrolides and quinolones) (used to treat infection).
- Antihistamines (used for allergic reactions).
- Cimetidine (used to treat heartburn).
- Ketoconazole (used to treat fungal infections).
- Metoprolol (used to treat high blood pressure and heart problems).
- Warfarin (used to prevent blood clots from forming).
- Diazepam and alprazolam (used to treat anxiety and panic disorders).
- Caffeine (used to restore mental alertness or wakefulness during tiredness or drowsiness).
- Carbamazepine (used to treat seizures and nerve pain).
- Tolbutamide (used to treat high blood sugar levels).

ODIVEN XR with food, drink and alcohol

See section 3.

You should avoid alcohol while you are taking ODIVEN XR.

Pregnancy and 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 health care provider for advice before taking ODIVEN XR.

The safety of ODIVEN XR has not been established during pregnancy and breastfeeding.

Driving and using machines

ODIVEN XR may cause side effects, such as dizziness, headache and drowsiness, and can affect your ability to drive a vehicle and use machines (see Possible side effects). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how ODIVEN XR affects you.

3. How to take ODIVEN XR

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

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

Adults (18 years and older)

The usual dose is 75 mg (one tablet of ODIVEN XR) once daily. Your doctor may increase your dose depending on your improvement of the condition being treated.

Your doctor may also start you on a higher dose of ODIVEN XR depending on the conditions you are being treated for.

Liver or kidney impairment

Your doctor will determine your dose based on the extent of your disease.

Method of administration

ODIVEN XR should be taken with food. Swallow the capsule whole, with a glass of water. Do not open, divide, crush, chew or place ODIVEN XR capsule in water.

ODIVEN XR should be taken once daily at more or less the same time each day, either in the morning or at night.

Your doctor will tell you how long your treatment with ODIVEN XR will last. Do not stop taking ODIVEN XR without talking to your doctor (see “If you stop taking ODIVEN XR”).

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

If you take more ODIVEN XR than you should

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

Signs and symptoms of an overdosage may include the following:

- Changes in your heartbeat (beating faster or slower).
- Changes in your state of wakefulness or awareness (from sleepiness to coma).
- Dilation of your pupils (the dark circular opening in the centre of the eye).
- Low blood pressure (light-headedness).
- Fits (seizures).
- Vomiting.
- Vertigo (sensation of spinning or swaying).

If you forget to take ODIVEN XR

If you miss a dose of ODIVEN XR, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten individual doses. If you have forgotten to take several doses, contact your doctor immediately.

If you stop taking ODIVEN XR

Do not stop taking ODIVEN XR or reduce your dose without first consulting your doctor, even if you feel better. If your doctor thinks that you no longer need ODIVEN XR, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop taking ODIVEN XR, especially when it is stopped suddenly, or the dose is reduced too quickly. Some patients may experience symptoms such as suicidal thoughts, aggressiveness, tiredness, dizziness, light-headedness, headache, sleeplessness, nightmares, dry mouth, loss of appetite, nausea, diarrhoea, nervousness, agitation, confusion, ringing in the ears, tingling or rarely electric shock sensations, weakness, sweating, seizures, or flu-like symptoms. Your doctor will advise you on how you should gradually discontinue ODIVEN XR treatment. If you experience any of these or other symptoms that are troublesome, ask your doctor for further advice.

4. Possible side effects

ODIVEN XR can have side effects.

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

If any of the following happens, stop taking ODIVEN XR 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.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ODIVEN 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.
- Changes in the way your heart beats, for example, if you notice it beating faster or skipping beats.
- Chest pain, shortness of breath, sweating, dizziness, fainting and irregular heartbeat.
- Signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, diarrhoea (frequent and watery bowel movements), coma, nausea (feeling sick), vomiting (being sick).
- Neuroleptic malignant syndrome (NMS), a life-threatening reaction, with signs and symptoms which may include fever or increased rate of respiration.
- Signs of recurrent infections such as a sore throat.
- Bleeding or bruising more easily than normal.
- Heavy vaginal bleeding shortly after giving birth.
- Passing more or less urine than is normal for you.
- Yellowing of the skin and eyes, also called jaundice.
- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks).
- Suicidal ideation, suicidal behaviours.

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

Tell your doctor if you notice any of the following:

Frequent:

- Increased cholesterol levels in the blood (determined by a blood test).

- Weight loss, decreased appetite.
- Confusion, feeling separated (or detached) from yourself, abnormal dreams, nervousness, agitation, sleeplessness.
- Dizziness, headache, drowsiness.
- Feeling of inner restlessness and a compelling need to be in constant motion such as rocking while standing or sitting.
- Involuntary trembling or shaking of hands and feet.
- Tingling or numbness of your hands and feet (pins and needles).
- Unusual muscle stiffness causing poor control of movement.
- Back pain.
- Metallic taste in the mouth, dry mouth.
- Visual disturbance including blurred vision, dilated pupils, inability of the eye to automatically change focus from distant to near objects.
- Ringing in the ears.
- High blood pressure, flushing.
- Yawning.
- Constipation (difficult evacuation of bowels), stomach pain.
- Excessive sweating and night sweats.
- Menstrual irregularities such as heavy and prolonged or increased irregular bleeding (females).
- Inability to develop or maintain an erection, abnormal ejaculation or orgasms (males), decreased libido, lack of orgasm.
- Abnormal physical weakness or lack of energy, fatigue, chills, pain.

Less frequent:

- Increased prolactin blood levels.
- Decrease in blood sodium levels.
- Over activity, racing thoughts and decreased need for sleep (mania).
- Hallucinations.

- Lack of interest, enthusiasm or concern.
- Grinding of the teeth.
- Over-excitement.
- Involuntary movements of the muscles.
- Impaired coordination and balance.
- Uncontrollable twitching or jerking movements.
- Temporary paralysis or weakness of muscles.
- Severe eye pain and decreased or blurred vision.
- Feeling dizzy when standing up too quickly.
- Altered taste sensation.
- Unexpected bleeding, e.g. bleeding gums, blood in the vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins).
- Sensitivity to sunlight.
- Temporary hair loss.
- Abnormal orgasm (females).
- Weight gain.

Frequency unknown:

- Vertigo (a sensation of feeling off-balance).
- Aggression.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ODIVEN XR.

5. How to store ODIVEN XR

- Store at or below 25 °C.
- Do not remove capsules from blister strips until required for use.
- Keep blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- 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 and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ODIVEN XR contains

The active substance in ODIVEN XR is venlafaxine (as venlafaxine HCl).

ODIVEN XR 37,5: Each extended-release capsule contains 37,5 mg venlafaxine (as venlafaxine HCl).

ODIVEN XR 75: Each extended-release capsule contains 75 mg venlafaxine (as venlafaxine HCl).

ODIVEN XR 150: Each extended-release capsule contains 150 mg venlafaxine (as venlafaxine HCl).

The other ingredients are gelatine, hydroxypropyl cellulose, microcrystalline cellulose, polymer coating (containing ethyl cellulose and hypromellose), potassium hydroxide (E 525), propylene glycol (E 1520), shellac (E 904), sodium laurilsulfate (SLS), talc and titanium dioxide (E 171).

ODIVEN XR 37,5 also contains iron oxide black (E 172).

ODIVEN XR 75 and ODIVEN XR 150 also contain iron oxide red (E 172).

Sugar free.

What ODIVEN XR looks like and contents of the pack

ODIVEN XR 37,5: White to off-white free flowing pellets, filled in size “3” hard gelatine capsule shells with an opaque grey cap and opaque white body, printed with “37.5 mg” in black ink on the body.

ODIVEN XR 75: White to off-white free flowing pellets, filled in size “1” hard gelatine capsule shells with an opaque peach cap and opaque peach body, printed with “75 mg” in black ink on the body.

ODIVEN XR 150: White to off-white free flowing pellets, filled in size “0” hard gelatine capsule shells with an opaque grey cap and opaque white body, printed with “150 mg” in black in on the body.

Transparent PVC/PVDC film and silver aluminium foil blister strip containing 10 capsules.

OR

Transparent OPA/PVC and silver aluminium foil blister strip containing 10 capsules.

Pack size: 30.

Holder of Certificate of Registration

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

Centurion 0157

Tel: 012 748 6400

This leaflet was last revised in

Not applicable.

Registration numbers

ODIVEN XR 37,5: 54/1.2/0072

ODIVEN XR 75: 54/1.2/0073

ODIVEN XR 150 54/1.2/0074

Date of registration

10 September 2024