PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

ODIVEN 37,5 tablets

ODIVEN 50 tablets

ODIVEN 75 tablets

Venlafaxine

Contains sugar:

45 mg lactose monohydrate per ODIVEN 37,5 tablet.

60 mg lactose monohydrate per ODIVEN 50 tablet.

90 mg lactose monohydrate per ODIVEN 75 tablet.

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

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

1. What ODIVEN is and what it is used for

ODIVEN is used in the treatment of depression, including depression associated with anxiety. It is also used to prevent the reoccurrence of depression episodes.

2. What you need to know before you take ODIVEN

Do not take ODIVEN

- If you are hypersensitive (allergic) to venlafaxine or any of the ingredients of ODIVEN (listed in section 6).
- If you are under the age of 18 years.
- If you are pregnant or breastfeeding your baby.
- If you are currently taking antidepressants called monoamine oxidase inhibitors (MAOIs, e.g. phenelzine, moclobemide), or have taken them in the last two weeks.

Warnings and precautions

Take special care with ODIVEN:

- Do not drink alcohol while being treated with ODIVEN as it can lead to extreme tiredness and unconsciousness. Concomitant use with alcohol and/or certain medicines can make your symptoms of depression and other conditions, such as anxiety disorders, worse.
- Severe adverse reactions have been reported when ODIVEN tablets are taken soon after discontinuation of an MAOI and when an MAOI is initiated soon after discontinuation of ODIVEN. This can lead to seizures and death.
- ODIVEN should not be taken for at least 14 days after stopping the MAOI treatment. Allow at least 7 days after stopping ODIVEN before starting an MAOI.
- Patients being treated with ODIVEN should, nevertheless, be observed closely for clinical worsening and suicidality, especially at the beginning of a course of therapy or at any time of dose changes, either increases or decreases.
- Do not stop taking your ODIVEN tablets without consulting your doctor. The dosage of these tablets must be slowly reduced over a period of two weeks in order to avoid serious side

effects.

- If you have a history of high blood pressure.
- 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 told you have an abnormal heart rhythm.
- If you have a history of 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 history of bleeding disorders (tendency to develop bruises or a tendency to bleed 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 section 4.6).
- If you have any kidney or liver problems.
- If you use other medicines that taken together with ODIVEN, could increase the risk of developing serotonin syndrome, a potentially life-threatening condition (see **Other medicines and ODIVEN**).
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- If you have any symptoms of sexual disorders, as ODIVEN may cause sexual problems (see section 4). In some cases, these symptoms have continued after stopping treatment.
- If you have any sensation of restlessness or an inability to sit or stand still. ODIVEN may cause these symptoms during the first few weeks of treatment. You should tell your doctor if this happens to you.
- If you experience a dry mouth while taking ODIVEN. This may increase the risk of tooth decay (caries). Therefore, you should take special care in your dental hygiene.
- If you have diabetes (high blood sugar). ODIVEN may alter your blood glucose levels. Therefore, the dosages of your diabetes medicines may need to be adjusted.

Children and adolescents

ODIVEN should not be used in children and adolescents under 18 years. Patients under 18 years 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 type of medicines, such as ODIVEN.

Other medicines and ODIVEN

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

Tell your doctor or pharmacist if you are currently using:

- Monoamine oxidase inhibitors (phenelzine, moclobemide), used in the treatment of depression.
- Linezolid (antibiotic), used to treat bacterial infections.
- Triptans (used to treat migraines), selective serotonin reuptake inhibitors or lithium (used to treat depression).
- Antiarrhythmics, e.g. quinidine, amiodarone, sotalol, dofetilide (used to treat heart rhythm disorders).
- Antipsychotics, e.g. thioridazine (used to treat psychiatric disorders).
- Macrolides, e.g. erythromycin (used to treat bacterial infections).
- Antihistamines (used to treat allergic reactions).
- Quinolone antibiotics, e.g. moxifloxacin (used to treat bacterial infections).
- Ketoconazole (used to treat fungal infections).
- Indinavir (antiviral treatment in HIV patients).
- Blood thinning tablets, e.g. warfarin (used to treat blood clotting disorders).
- Alcohol.
- Haloperidol and risperidone (antipsychotic medicine) (used to treat psychiatric disorders).
- Cimetidine (used to treat heartburn).
- Metoprolol (used to treat high blood pressure).

- Diazepam (sedative agent) (used to treat certain seizure disorders and help relax muscles or relieve muscle spasm).
- Imipramine (used to treat depression).
- Alprazolam (used to treat anxiety and/or panic disorders).
- Carbamazepine (used to manage and treat epilepsy).
- Tolbutamide (used to treat high sugar levels).
- Oral contraceptives (use to prevent unplanned pregnancies).

ODIVEN with food, drink and alcohol

It is recommended that ODIVEN be taken with food.

Avoid the consumption of alcohol while taking ODIVEN tablets.

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 ODIVEN.

Driving and using machines

ODIVEN may cause dizziness or drowsiness. Do not drive a vehicle or use any tools or machines until you know how ODIVEN tablets affect you.

Important information about some of the ingredients of ODIVEN

ODIVEN contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ODIVEN tablets.

ODIVEN contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say it is essentially sodium free.

3. How to take ODIVEN

Always take ODIVEN exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of ODIVEN is too strong or too weak, talk to your doctor or pharmacist.

The usual recommended dose is 75 mg per day given in two divided doses (37,5 mg twice daily). The dose may be increased to 150 mg per day given in two divided doses (75 mg twice daily), if necessary.
The maximum recommended dose of 375 mg should not be exceeded.

Patients with renal and/or hepatic impairment should receive lower doses of ODIVEN.
The total daily dose of ODIVEN must be reduced by 50 % in patients with moderate hepatic impairment.
No specific dosage adjustments of ODIVEN are recommended based on patient age.

If you take more ODIVEN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
The symptoms of a possible overdose may include a rapid heartbeat, low blood pressure, low blood sugar, spinning sensation, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures or fits and vomiting.

If you forget to take ODIVEN

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.
If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

4. Possible side effects

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

If any of the following happens, stop taking ODIVEN 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. 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:

- Fast or irregular heartbeat, chest pain, difficulty in breathing.
- Agitation, confusion, mood and mental changes.
- Ringing or buzzing in ears.
- Difficulty urinating or holding urine.
- Signs and symptoms of serotonin syndrome, which may include restlessness, hallucinations, loss of coordination, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting.
- In its 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).
- Suicidal ideation and suicidal behaviours; cases of suicidal ideation and suicidal behaviours

have been reported during venlafaxine, as in ODIVEN, therapy or early after treatment discontinuation (see **What you need to know before you take ODIVEN**).

- Unexplained muscle pain, tenderness or weakness. This may be a sign of rhabdomyolysis.
- Eye problems, such as blurred vision, dilated pupils.
- Stress cardiomyopathy, including symptoms such as chest pain, shortness of breath, dizziness, fainting, irregular heartbeat.
- Coughing, wheezing and shortness of breath which may be accompanied by a high temperature.
- Black (tarry) stools or blood in stools.
- Itchiness, yellow skin or eyes, or dark urine, which may be symptoms of inflammation of the liver (hepatitis).
- Nerve problems, such as dizziness, pins and needles, movement disorder (muscle spasms or stiffness), seizures or fits.
- Prolonged bleeding – if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop.
- Severe stomach or back pains (which could indicate a serious problem in the gut, liver or pancreas).
- Excessive water intake (known as SIADH).
- Severe eye pain and decreased or blurred vision.
- Low blood sugar. The warning signs of low blood sugar may come on suddenly. They can include cold sweat, cool pale skin, headache, fast heartbeat, feeling sick (nausea) or very hungry, changes in vision, feeling sleepy or weak, feeling nervous, anxious or confused, difficulty concentrating or shaking.

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:

- Headache.

- High blood pressure.
- Visual disturbances.
- Abnormal dreams, anxiety or nervousness, trouble sleeping.
- Constipation, diarrhoea, heartburn, nausea.
- Weight loss, loss of appetite.
- Sexual dysfunction.

Less frequent side effects:

- Prolonged bleeding, which may be a sign of reduced number of platelets in your blood, leading to an increased risk of bruising or bleeding.
- Unexpected bleeding, bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins).
- Overactivity, racing thoughts and decreased need for sleep (mania).
- Hallucinations, feeling separated (or detached) from reality, abnormal orgasm, lack of feeling or emotion, feeling over-excited, grinding of the teeth.
- Fainting, involuntary movements of the muscles, impaired coordination and balance.
- Feeling dizzy (particularly when standing up too quickly), decrease in blood pressure.
- Vomiting blood, black tarry stools (faeces) or blood in stools, which can be a sign of internal bleeding.
- Sensitivity to sunlight, bruising, abnormal hair loss.
- Inability to control urination.
- Slight changes in blood levels of liver enzymes.
- Muscle tension, change in sense of taste.
- Disorientation and confusion often accompanied by hallucinations (delirium).
- Decrease in blood sodium levels.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store ODIVEN

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the blisters and containers. Decomposed products may be toxic.
- 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 contains

The active substance is venlafaxine hydrochloride.

ODIVEN 37,5: Each tablet contains venlafaxine hydrochloride equivalent to 37,5 mg venlafaxine.

ODIVEN 50: Each tablet contains venlafaxine hydrochloride equivalent to 50 mg venlafaxine.

ODIVEN 75: Each tablet contains venlafaxine hydrochloride equivalent to 75 mg venlafaxine.

The other inactive ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (Type A), iron oxide yellow (E172), iron oxide red (E172) and magnesium stearate.

What ODIVEN looks like and contents of the pack

ODIVEN 37,5: Peach coloured, round, flat, bevelled edge, uncoated tablets with a bisect on one side; one side of the bisect is debossed with the logo "ZC" and other side is debossed with "65", the other side is plain.

ODIVEN 50: Peach coloured, round, flat, bevelled edge, uncoated tablets with a bisect on one side; one side of the bisect is debossed with the logo "ZC" and other side is debossed with "66", the other side is plain.

ODIVEN 75: Peach coloured, round, flat, bevelled edge, uncoated tablets with a bisect on one side; one side of the bisect is debossed with the logo "ZC" and other side is debossed with "67",

the other side is plain.

ODIVEN 37,5, ODIVEN 50 and ODIVEN 75 tablets are packed in an aluminium/PVC/PVDC foil blister strip containing ten tablets.

Pack sizes: 10, 30, 60 or 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Zydus Healthcare SA (Pty) Ltd

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0157

Tel: 012 748 6400

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ODIVEN 37,5: 41/1.2/0440

ODIVEN 50: 41/1.2/0441

ODIVEN 75: 41/1.2/0442

Date of registration

09 July 2007

Access to the corresponding Professional Information

The Professional Information is available on https://www.zydus.co.za/ or may be requested by contacting 012 748 6400.