PROPOSED PATIENT INFORMATION LEAFLET FOR DESVENLAFAXINE 50 MG

AND 100 MG EXTENDED RELEASE TABLETS

SCHEDULING STATUS

S4

DEPVEN XL 50 mg and 100 mg Extended Release Film coated Tablets.

Each film-coated tablet contains desvenlafaxine succinate equivalent to desvenlafaxine 50 mg and 100 mg.

Read all of this leaflet carefully before you start taking DEPVEN XL

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

1. What DEPVEN XL is and what it is used for

DEPVEN XL is an anti-depressant medicine which falls under the class of selective serotonin and norepinephrine reuptake inhibitors (SNRI's).

DEPVEN XL is indicated for the treatment of major depressive disorder.

2. What you need to know before you take DEPVEN XL

Do not take DEPVEN XL:

- If you are hypersensitive (allergic) to desvenlafaxine, venlafaxine, or any of the ingredients of DEPVEN XL.
- If you are using other antidepressant medicines which fall under the class of monoamine oxidase inhibitors (ask your doctor or pharmacist if you are uncertain).
- If you are less than 18 years of age.
- If you are pregnant or are a mother breastfeeding newborn.

Warnings and precautions

Special care should be taken with DEPVEN XL:

Tell your doctor:

- If you experience symptoms such as anxiety, panic attacks, lack of sleep, feeling irritable, unfriendliness, aggressiveness, a tendency to act on instinct, difficulty to stay still, abnormal energy levels or suicidal thoughts.
- If you have been diagnosed with or have a family history of a mood disorder called bipolar disorder. Symptoms include mood swings, sadness, irritability, risk-taking behaviour, unwanted thoughts, lack of concentration, depression, and paranoia.

- If you have been diagnosed with or have a family history of a mood disorder called mania or hypomania. Symptoms include increased sexual desire, racing thoughts, inappropriate irritability, inappropriate social behaviour, and increased talking speed or volume.
- If you develop symptoms such as feeling anxious or nervous (agitation), seeing or hearing things that do not exist (hallucinations), a deep state of unconsciousness (coma), rapid heartbeat, constantly changing blood pressure, abnormally high body temperature, overactive reflexes, inability to use different parts of the body efficiently, nausea (the urge to vomit), vomiting, and diarrhoea.
- If you have recently stopped taking other anti-depressant medicines. Especially those under the class of monoamine oxidase inhibitors such as moclobemide or tranylcypromine. Your doctor will need to allow for at least 14 days to pass before starting treatment with DEPVEN XL after stopping these medicines.
- If you have been diagnosed with a condition of the eye called glaucoma.
- If you have been diagnosed with or have a family history of heart disease, including heart attack.
- If you notice blood in your stool or vomit.
- If you have recently stopped taking DEPVEN XL and experience symptoms such as dizziness, nausea, headaches, moodiness, anxiety, feeling tired or weak, feeling confused, constantly changing emotions, difficulty sleeping and seizures (fits).

- If you been diagnosed with high blood pressure or experience symptoms of increased blood pressure such as chest pain, vision problems, irregular heartbeat, headache, confusion and/or feeling tired.
- If you are taking other anti-depressant medicines which contain venlafaxine.
- If you have been diagnosed with or have a family history of cholesterol or any other fat disorder.
- If you have been diagnosed with epilepsy or any other disorder which may result in seizures (fits).
- If you are taking any blood thinning medicines such as aspirin or warfarin or if you notice sudden unexplained bleeding.
- If you have been diagnosed with low blood sodium (hyponatraemia) or inappropriate secretion of antidiuretic hormone. These conditions occur more in dehydrated and elderly patients.
- If you experience shortness of breath, cough or chest discomfort. These are symptoms associated with a form of lung disease and pneumonia therefore your doctor may need to do certain tests to confirm a diagnosis.
- If you feel lightheaded when standing up, especially if you are over the age of 65.

DEPVEN XL should not be taken by children younger than 18 years of age.

Other medicines and DEPVEN XL

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

The following medicines interact with DEPVEN XL in the following ways:

- DEPVEN XL should not be used with antidepressant medicines which fall under the class of monoamine oxidase inhibitors (ask your doctor or pharmacist if you are uncertain). These could increase side effects such as nausea, vomiting, dizziness, seizures, abnormally increased body temperature, sweating and even death.
- Caution should be exercised if you are using any other medicines which act on the central nervous system (Brain and spinal cord) as safety has not been evaluated. Ask your doctor or pharmacist if you are uncertain whether medicines you are taking act on the central nervous system.
- Concomitant use of DEPVEN XL with other medicines which affect serotonin levels such as selective serotonin reuptake inhibitors (SSRI's), other SNRI's, lithium, sibutramine, tramadol, St Johns' wort *(hypericum perforatum),* and pethidine may cause a condition called serotonin syndrome which may be potentially life threatening.
- Co-administration of DEPVEN XL with blood thinning medicines may increase the risk of bleeding.
- DEPVEN XL levels may be increased when taken with medicines which decrease the CYP3A4 liver enzyme which is involved it its metabolism. These medicines include clarithromycin, ketoconazole and itraconazole.
- Concentrations of medicines which are metabolised by the liver enzyme CYP2D6 such as desipramine, atomoxetine, dextromethorphan, metoprolol, nebivolol

perphenazine and tolterodine may be increased by co-administration with DEPVEN XL.

- Concomitant use of DEPVEN XL with medicines such as midazolam which are metabolised by CYP3A4 enzymes may lead to decreased exposure to those medicines.
- Taking DEPVEN XL may cause false positive urine tests for substances such as phencyclidine (PCP) and amphetamine. Your doctor or other health professional may need to do other confirmatory tests to exclude the presence of these substances in your bloodstream.

DEPVEN XL with food and drink and alcohol

DEPVEN XL can be taken with or without food.

DEPVEN XL should not be taken with alcohol as it may cause unwanted side effects.

Pregnancy and 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 healthcare professional for advice before taking DEPVEN XL.

The safety of DEPVEN XL in pregnancy has not been established. If DEPVEN XL is used until, or shortly before birth, unwanted side effects may occur in the newborn.

Do not Take DEPVEN XL if you are breastfeeding your baby.

Driving and using machines

DEPVEN XL may interfere with your judgement, thinking and motor skills which may in turn affect your ability to drive or operate machines.

It is not always possible to predict to what extent DEPVEN XL 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 DEPVEN XL affects them.

3. How to take DEPVEN XL:

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

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

The usual dose is one 50 mg tablet, taken once daily with or without food, at the same time each day. Your doctor may increase your dose to a maximum of 100 mg daily.

Your doctor will tell you how long your treatment with DEPVEN XL will last. Do not stop treatment because this may cause resistance to the medicine. If you have the impression that the effect of DEPVEN XL is too strong or too weak, tell your doctor or pharmacist.

The tablets must be swallowed whole with a glass of water.

Do not crush or chew them.

Follow these instructions closely unless your doctor has advised you otherwise.

If you take more DEPVEN XL than you should

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

Human experience of an overdose of DEPVEN XL is limited.

The symptoms of an overdose may include:

- An abnormally fast heartbeat,
- Feeling sleepy or going into a coma,
- Seizures (fits),
- Dilation of the pupil of the eye,
- Low blood pressure,
- A breakdown of muscle tissue,
- Motion sickness,
- Symptoms associated with serotonin syndrome such as anxiety.

If you experience any of these symptoms, contact your doctor, pharmacist or poison control centre immediately.

If you forget to take DEPVEN XL

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

4. Possible side effects

DEPVEN XL can have side effects.

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

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

- Swelling of the hands, feet, face, lips or throat which may cause difficulty swallowing or breathing.
- Severe itchy rash.
- If you experience a very fast or unusual heartbeat, chest pain or any heart related symptoms.
- Suicidal thoughts
- Bleeding.

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

- Seizures or convulsions (fits)
- Anxiety

- Seeing and hearing things that do not exist (hallucinations)
- Diarrhoea or abnormal stools
- Vision problems
- Inability to urinate
- Increased blood pressure
- A general feeling of weakness.

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:

- Decreased appetite,
- Difficulty sleeping,
- Abnormal dreams,
- Feeling nervous,
- Decreased interest in sexual intercourse,
- Inability to reach an orgasm,
- Dizziness,
- Headache,
- Sleepiness,
- Tingling sensation,
- Impaired sense of taste,
- Disturbance in attention,
- Motion sickness,

- Dilation of the eye pupils,
- Ringing sound in the ear
- Hot flushes,
- Yawning,
- Nausea (the urge to vomit)
- Dry mouth,
- Constipation (difficulty passing stools)
- Vomiting,
- Muscle stiffness,
- Difficulty getting an erection,
- Difficulty ejaculating,
- Feeling tired,
- Feeling cold,
- Feeling jittery,
- Feeling irritable,
- Weight gain,
- Weight loss.

Less frequent side effects:

- Allergic reactions,
- Low blood sodium levels (determined by blood tests)
- Physical and mental symptoms when stopping or reducing the dose of DEPVEN XL,

- Abnormal orgasm,
- Unreal thoughts and feelings,
- Fainting,
- Uncontrollable contractions of the muscles,
- Light-headedness especially when standing up,
- Bleeding from the nose,
- Loss of hair,
- Being sensitive to light,
- Difficulty urinating
- Coldness of the extremities
- Proteins in the urine (determined through urine tests),
- Ejaculation problems,
- Sexual dysfunction,
- Increased blood cholesterol,
- Increased fat content in blood,
- Abnormal liver function tests,
- Increased blood prolactin (determined through blood tests).

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

"**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/publications/index/8, or to Cipla Medpro (Pty) Ltd by email: drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of DEPVEN XL.

5. How to store DEPVEN XL

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not refrigerate.

Store in the original packaging.

Keep the container tightly closed.

Protect from moisture.

Do not store in a bathroom.

Do not use DEPVEN XL after the expiry date stated on the carton.

Return all unused medicines to your pharmacist.

Do not dispose unused medicines in drains or sewage systems. (e.g. Toilets)

6. Contents of the pack and other information

The active substance is

- Desvenlafaxine 50 and 100 mg.

The other ingredients are:

- Hypromellose (Benecel K100M PHARM CR)
- Hypromellose (Methocel K100LV CR)
- Magnesium stearate
- Microcrystalline cellulose (Comprecel M 101)
- Povidone K-90
- Purified water
- Talc
- Opadry Pink 03F84770 (for 50 mg formulation)
- Opadry Brown 03F86990 (for 100 mg formulation)

Contents of the film-coating (opadry):

Opadry Pink 03F84770

- HPMC 2910/Hypromellose (6cP)
- Iron oxide red.
- Macrogol/ PEG 6000
- Talc
- Titanium dioxide

Opadry Brown 03F86990

- HPMC 2910/Hypromellose (6cP)
- Iron oxide black

- Iron oxide red.
- Macrogol/ PEG 4000
- Titanium dioxide.

What DEPVEN XL looks like and contents of the pack

DEPVEN XL 50 mg extended release tablets are light pink coloured, round, biconvex, film coated tablets, debossed with ‘50’ on one side and plain on other side.

DEPVEN XL 100 mg extended release tablets are dark brown to red coloured, round, biconvex, film coated tablets, debossed with ‘100’ on one side and plain on other side.

DEPVEN XL Extended Release Tablets are packed in Blister and HPDE bottle pack(s). Such blisters and/or HDPE bottles are further packed in a Carton along with Pack Insert.

Holder of certificate of registration

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DEPVEN 50 XL: 53/1.2/0048
DEPVEN 100 XL: 53/1.2/0049

Access to the corresponding professional information

The professional information is contained in the packaging of DEPVEN XL.