PATIENT INFORMATION LEAFLET

EXLOV XR RANGE

SCHEDULING STATUS:

S5

EXLOV XR 50 mg extended release tablets

EXLOV XR 100 mg extended release tablets

Desvenlafaxine

EXLOV XR tablets are sugar free.

Read all of this leaflet carefully before you start taking EXLOV XR

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

1. What EXLOV XR is and what it is used for

EXLOV XR contains desvenlafaxine and belongs to the class of antidepressant medicines known as selective serotonin and noradrenaline (norepinephrine) reuptake inhibitors (SNRIs).

EXLOV XR works on the central nervous system (CNS) to elevate mood by increasing the amount of two neurotransmitters called serotonin and noradrenaline (norepinephrine) that are available in certain parts of the brain. Serotonin and noradrenaline (norepinephrine) are chemical messengers that allow certain nerves in the brain to work.

EXLOV XR is used to treat major depressive disorder.

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

Do not take EXLOV XR:

- if you are hypersensitive (allergic) to desvenlafaxine, venlafaxine hydrochloride, or any of the other ingredients of EXLOV 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 including an antibiotic called linezolid. Taking an MAOI together with EXLOV XR can cause serious or even life-threatening side effects.

  You must wait at least 7 days after you stop taking EXLOV XR before you take any MAOI. Serious side effects are known to occur if you take EXLOV XR soon after stopping an MAOI or if you take an MAOI soon after stopping EXLOV XR. A potentially life-threatening condition or neuroleptic malignant syndrome (NMS)-like reactions may occur with desvenlafaxine treatment. You may experience overactive reflexes (muscle twitching and sudden muscle jerks), sweating, nausea, vomiting, flushing, dizziness, abnormally high body temperature and seizures (fits)
- if you are 18 years old or younger
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with EXLOV XR:

- if your depression gets worse, especially in the first few weeks of treatment or if your dose has changed. Contact your doctor if you have thoughts of suicide or self-harm, or if you experience any of the following symptoms: anxiety or agitation, panic attacks, difficulty sleeping, irritability, hostility (aggressiveness or impulsiveness), restlessness or unusual changes in behaviour
- if you or anyone in your family has a history of mania or bipolar disorder (feeling overexcited or euphoric)
- if you experience symptoms such as changes to mental health, confusion, headache, shivering, diarrhoea, muscle stiffness, high fever, agitation, hallucinations, sweating, fainting, rapid or irregular heartbeat, loss of muscle coordination and muscle twitches nausea, vomiting, and seizures as this may be signs of something called serotonin syndrome. Neuroleptic malignant syndrome and serotonin syndrome are serious and may be life-threatening, if you think you might have either of these syndromes while taking EXLOV XR, call your doctor immediately or go to the emergency department of nearest hospital. If you have severe or rapidly worsening symptoms, seek emergency treatment immediately
- if you have eye problems, such as glaucoma or increased pressure in the eye, your doctor will monitor your condition as EXLOV XR may cause dilation of the pupils (mydriasis)
- if you are discontinuing treatment with EXLOV XR, your doctor will gradually reduce your daily dose and monitor you, in order to prevent unwanted side effects
- if you are pregnant and your doctor has prescribed EXLOV XR for you in the month before your baby is due, there is a risk of excessive bleeding after childbirth.

Discuss the following precautions with your doctor before taking EXLOV XR:

- if you have recently suffered a heart attack or suffer from a heart disease as special care is recommended
- if you have a history of high blood pressure, EXLOV XR may increase blood pressure levels. It is advisable to check your blood pressure at regular intervals
- if you have a condition that affects the blood vessels and blood supply to the brain (cerebrovascular disease) as EXLOV XR may increase your blood pressure
- if you suffer from high cholesterol as these levels will need to be closely monitored during treatment with EXLOV XR
- if you suffer from or have a history of seizures (fits) as EXLOV XR may increase the risk for seizures
- if you have a tendency to develop bruises or a tendency to bleed easily (history of bleeding disorders), or if you are taking other medicines that may increase the risk of bleeding e.g. aspirin (used for pain or headache) and warfarin (used to prevent blood clots)
- if you are dehydrated, have recently suffered from diarrhoea, or vomiting, are elderly, or take diuretics (water tablets) as special care is needed. EXLOV XR may cause your body to retain water and upset your body's balance of electrolytes (syndrome of inappropriate antidiuretic hormone - SIADH)
- EXLOV XR may cause sexual function problems like decreased sex drive, delayed ejaculation or problems achieving erections (see Possible side effects)
- if you are 65 years or older, there is a possibility of greater sensitivity to EXLOV XR
- if you are going for electroconvulsive therapy used to treat patients with severe depression or bipolar disease unresponsive to other treatment
- if you are going for urine drug screening tests for phencyclidine (PCP) or amphetamine as EXLOV XR may cause false positive test results.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you can sometimes behave aggressively, be irritable or have thoughts of harming or killing yourself. These may be increased when you first start taking antidepressants, since these medicines take time to work (usually about two weeks, but sometimes longer).

If you have thoughts of harming or killing yourself at any time, contact your doctor 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 should 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

Do not give EXLOV XR to children and adolescents under 18 years because of the risk of aggressive behaviour, irritability, agitation, thoughts of harming themselves and suicide.

Other medicines and EXLOV 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 EXLOV XR are:

- monoamine oxidase inhibitors (MAOIs) which are used to treat depression or Parkinson's disease must not be taken with EXLOV XR (see Do not take EXLOV XR). Tell your doctor if you are taking or have stopped taking an MAOI within the last 14 days, since continuation with both medicines may result in a serious life-threatening condition
- other medicines for anxiety, panic, stress, and sleep disorders (medicines that work on the central nervous system)

- serotonin syndrome, a potentially life-threatening condition, may develop with EXLOV XR treatment, particularly if you take other medicines that affect serotonin levels at the same time. Symptoms of serotonin syndrome that you may experience are changes to mental health, confusion, seeing things that are not really there (hallucinations), agitation or restlessness, sweating abnormalities, dizziness and fainting upon standing, rapid or irregular heartbeat, stomach problems, loss of muscle coordination and muscle twitches

  These medicines include:

  - triptans (used to treat migraines)
  - other medicines called SNRIs, SSRIs, tricyclics, or lithium (used to treat depression)
  - sibutramine (used for weight loss)
  - tramadol or pethidine (for pain)
  - St. John's Wort (also called *Hypericum perforatum*), a herbal medicine used to treat mild depression
  - products containing tryptophan (used for sleep problems and depression)
  - linezolid (antibiotic used to treat infections).

The following medicines may also interact with EXLOV XR and should be used with caution:

EXLOV XR used together with:

- ketoconazole (an antifungal medicine), may result in higher levels of EXLOV XR in the blood
- desipramine (to treat mild to moderate pain) and morphine (used in the treatment severe pain) may cause higher levels of EXLOV XR
- midazolam (used prior to surgery) taken with EXLOV XR may result in lower levels of midazolam
- tamoxifen (used in the treatment of breast cancer)
- aripiprazole (used in the treatment bipolar disorder).

A false positive urine test result for phencyclidine (PCP) and amphetamines may occur when taking EXLOV XR. A test to confirm results is advised.

EXLOV XR with food, drink, and alcohol

You may take EXLOV XR with or without food. Avoid drinking alcohol while you are taking EXLOV XR.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before using EXLOV XR.
Do not take EXLOV XR if you are pregnant, planning to become pregnant or think you may be pregnant. If you become pregnant, please contact your doctor or healthcare provider immediately.
There is a risk that newborn babies whose mothers have been taking EXLOV XR, may experience several problems such as breathing difficulties, rapid breathing, seizures, lack of oxygen in the blood, vomiting and diarrhoea.

If you take EXLOV 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 EXLOV XR so they can advise you.
Do not take EXLOV XR if you are breastfeeding your baby as EXLOV XR passes into breast milk. There is a possibility that the breastfed baby may be affected.

Driving and using machines

EXLOV XR may lower your ability to react quickly and appropriately to sudden and unexpected events. Make sure you know how you react to EXLOV XR before driving a vehicle or operating machinery.

It is not always possible to predict to what extent EXLOV XR 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 EXLOV XR affects them.

3. How to take EXLOV XR

Do not share medicines prescribed for you with any other person.
Always take EXLOV XR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

EXLOV XR should be taken at approximately the same time each day. Tablets must be swallowed whole with fluid and should not be divided, crushed, chewed, or dissolved.

Adults:
The usual dose is 50 mg taken once daily, with or without food, with a maximum dose of 100 mg per day. Your doctor will gradually increase your dose if necessary.

You should inform your doctor if you have kidney problems as you may need a lower dose of EXLOV XR.
Your doctor will tell you how long your treatment with EXLOV XR will last. Do not stop treatment early because unwanted side effects may occur (see If you stop taking EXLOV XR).
If you have the impression that the effect of EXLOV XR is too strong or too weak, tell your doctor or pharmacist.

If you take more EXLOV 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.

If you forget to take EXLOV XR

If you forget to take EXLOV XR, talk to your doctor or nurse immediately. Do not take a double dose to make up for forgotten individual doses.

If you stop taking EXLOV XR

If you stop taking EXLOV XR suddenly, you may experience side effects such as dizziness, nausea, headache, tiredness, irritability, agitation or anxiety, confusion, lack of coordination, sleeping problems, prickling, or burning sensation on the skin, electric shock-like sensations, diarrhoea, abnormal dreams, fatigue, and excessive sweating. Do not stop taking EXLOV XR without consulting your doctor as your doctor will slowly decrease your dose of EXLOV XR to help avoid these side effects.

Switching to EXLOV XR from other antidepressants

If you are already using an antidepressant medicine (including venlafaxine) prescribed by your doctor, you may experience side effects when discontinuing it in order to switch to EXLOV XR. Your doctor will gradually reduce the dose of your initial antidepressant medicine to help reduce these side effects.

4. Possible side effects

EXLOV XR can have side effects.

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

If any of the following happens, stop using EXLOV 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 EXLOV 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:

- signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of coordination, fast or irregular heartbeat, palpitations; increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, nausea, vomiting
- less urine than is normal for you, difficulty passing urine
- Stevens-Johnson syndrome or other serious skin disorder (begins with fever and flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters)
- intense chest pain (stress cardiomyopathy)
- inflammation of the pancreas characterised by severe upper abdominal pain, swollen and tender abdomen, nausea, vomiting, fever, and fast heartbeat (acute pancreatitis).

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:

- loss of appetite
- trouble sleeping, anxiety, abnormal dreams, nervousness, irritability
- decreased sex drive, problems achieving orgasm or erection, delayed ejaculation

- dizziness, headache, drowsiness, excess sleepiness, involuntary shaking or movement, pins, and needles, altered sense of taste, disturbances in concentration
- blurred vision or dilation of the pupils
- ringing in the ears, sensation of spinning or feeling off balance
- fast or irregular heartbeat, palpitations
- sudden feeling of warmth (hot flush), increase in blood pressure
- yawning
- nausea, dry mouth, constipation, diarrhoea, vomiting
- excessive sweating
- muscle stiffness
- tiredness, chills, lack of energy and strength (asthenia), feeling jittery
- weight gain, weight loss.

Less frequent side effects:

- low levels of sodium in the blood
- feeling disconnected or detached from your thoughts and body, feeling overexcited or overly irritable with increased energy (hypomania), hallucinations, feeling very happy, elated, or overjoyed, talking very quickly, feeling full of energy, being easily distracted, disturbed or illogical thinking (mania)
- temporary loss of consciousness (syncope), convulsions, uncontrollable muscle contraction (dystonia), movement disorder (extrapyramidal disorder)
- fainting or dizziness after standing, cold hands and feet
- nose bleeds
- abnormal hair loss, sensitivity to sunlight, severe, painless, swelling under the skin (angioedema)

- abnormal quantities of protein in the urine, difficulties passing urine
- sexual function problems, abnormal ejaculation
- increased cholesterol, abnormal liver function test, increased prolactin levels (a hormone that stimulates breast development and milk production
- bleeding or bruising more easily than usual.

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

- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see section 2 – Warnings and precautions) 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, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by using either of the links: https://www.sahpra.org.za/Publications/Index/8 or https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

By reporting side effects, you can help provide more information on the safety of EXLOV XR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store EXLOV 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 EXLOV XR contains:

The active substance is desvenlafaxine.

EXLOV XR 50 mg: Each extended release tablet contains desvenlafaxine benzoate equivalent to 50 mg desvenlafaxine.

EXLOV XR 100 mg: Each extended release tablet contains desvenlafaxine benzoate equivalent to 100 mg desvenlafaxine.

The other ingredients are

Colloidal silicon dioxide, hypromellose, microcrystalline cellulose, stearic acid, talc, FD&C Yellow #6/Sunset Yellow FCF (E 110) Aluminium Lake (100 mg tablet only), iron oxide red, iron oxide yellow (50 mg tablet only), macrogol, polyvinyl alcohol, titanium dioxide.

What EXLOV XR looks like and contents of the pack

EXLOV XR 50 mg: Light pink, biconvex, round shaped extended release film coated tablets debossed with "DV" on one side and "50" on the other side.

EXLOV XR 100 mg: Reddish-orange, biconvex, round shaped extended release film coated tablets, debossed with "DV" on one side and "100"on the other side.

EXLOV XR tablets are packed in clear PVC/Aclar Aluminium foil blister packs, inside a carton. Each carton contains 30 tablets.

Holder of Certificate of Registration

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