PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

Dexinor 50 XR 50 mg extended-release tablets

Dexinor 100 XR 100 mg extended-release tablets

Desvenlafaxine benzoate

Sugar free

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

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

Dexinor XR tablets are indicated for the treatment of major depressive disorder (MDD).

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

Do not take Dexinor XR

- If you are hypersensitive (allergic) to desvenlafaxine benzoate or any of the other ingredients of Dexinor XR (listed in section 6).
- You should not take Dexinor XR together with other so-called MAO inhibitors (MAOI), a special group of anti-depressants. If you have been taking an MAOI then you should only start taking Dexinor XR when there has been an interval of at least 14 days since you stopped taking the MAOI. If you stop taking Dexinor XR you should wait at least 7 days before taking an MAOI. Serious reactions may occur, such as tremor, muscle twitching, sweating, nausea, vomiting, flushing (redness in the face), dizziness, elevated body temperature, seizures and death.
- You are less than 18 years of age.
- If you are pregnant or breastfeeding.

Warnings and precautions

Take special with Dexinor XR:

- Especially at the start of treatment and when the dose is altered, the doctor will observe whether there is deterioration in your symptoms.
- It has not been determined whether Dexinor XR is safe and effective in children under the age of 18 years. There have been reports of hostile behaviour, suicidal tendencies and self-harm when medicines from the same group of medicines to which Dexinor XR also belongs is used in children under 18 years of age.
- Mania has been reported in patients using Dexinor XR. Therefore, Dexinor XR should be used with caution, especially if you have a history or family history of mania.
- Serotonin syndrome, which is a potentially life-threatening medicine reaction that causes the body to have too much serotonin (a chemical produced by nerve cells) may occur. Symptoms may include: agitation, hallucinations, coma, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, loss of

coordination, nausea, vomiting, diarrhoea. Serotonin syndrome most often occurs when two medicines that affect the body's level of serotonin are taken together at the same time. The medicines cause too much serotonin to be released or to remain in the brain area. Examples of medicines that cause this reaction when used together with Dexinor XR are: triptans (migraine medicines) and antidepressant medicines such as selective serotonin reuptake inhibitors (SSRIs), selective serotonin/norepinephrine reuptake inhibitors (SSNRIs) and monoamine oxidase inhibitors (MAOIs). Tell your doctor if you think you are using any of these medications.

- Mydriasis (dilation of pupils) can occur when using Dexinor XR. Therefore, patients with high internal pressure in the eyes or those with a high risk of narrow angle glaucoma (damage to the nerve of the eye) should be carefully monitored.

The following are precautions for use of Dexinor XR to be discussed with your doctor if you have or have had any of the following:

- Your blood pressure can rise during treatment with Dexinor XR, especially if you are taking high doses. It is therefore advisable to check your blood pressure at regular intervals.
- If you are elderly, your blood pressure may drop on standing up, causing
- you to feel dizzy or faint.
- If you have recently suffered a heart attack or suffer from a heart disease which has not been stabilised, special care is advised and the necessary dose for you should be especially carefully adjusted. Because high cholesterol levels may occur under long-term treatment with Dexinor XR, cholesterol examinations should be taken into consideration.
- Please inform your doctor if you suffer or have previously suffered from seizures (especially epilepsy) because Dexinor XR should then only be used with care.
- Withdrawal symptoms can occur after treatment with Dexinor XR depending on the dose which has been taken and the duration of treatment, especially if the treatment is

ended suddenly. It is recommended to end treatment by reducing the dose in steps.

- It is possible that there is increased risk of skin or mucous membrane bleeding during treatment with Dexinor XR. Please inform your doctor if you know that you suffer from blood clotting disorders.
- Low sodium blood levels (hyponatraemia) and/or the so-called “syndrome of inappropriate ADH secretion” (SIADH) can occur under treatment with Dexinor XR. When hyponatraemia is severe or acute in onset, symptoms of cerebral oedema occur (irritability, confusion, seizures and coma). Usually, patients are affected who have reduced quantities of circulating blood or whose bodies contain too little water, such as elderly patients or patients who are being treated with diuretics.
- If you have lung problems including difficulty breathing, cough or chest discomfort.
- Greater sensitivity to Dexinor XR in older patients cannot be ruled out.

Children and adolescents

Safety and efficacy in children under 18 years of age has not been established.

Other medicines and Dexinor XR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). The use of Dexinor XR with these medicines may cause undesirable interactions.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

Monoamine oxidase inhibitors (MAOIs):

If Dexinor XR and certain other anti-depressants belonging to the group of “MAOI” are taken at the same time or immediately after one another, this can give rise to dangerous interactions which can only be controlled with difficulty.

If you have been taking an MAOI then you should only start taking Dexinor XR when there has been an interval of at least 14 days since you stopped taking the MAOI. If you stop taking

Dexinor XR you should wait at least 7 days before taking an MAOI. Serious reactions may occur, such as tremor, muscle twitching, sweating, nausea, vomiting, flushing (redness in the face), dizziness, elevated body temperature, seizures and death.

Serotonin syndrome:

Using Dexinor XR with certain medications may cause a serious and potentially life-threatening reaction called serotonin syndrome (see also the section called 'Take special care with Dexinor XR'). These medications include: triptans (migraine medicines); other medicines to treat depression such as selective serotonin reuptake inhibitors (SSRIs), selective serotonin/norepinephrine reuptake inhibitors (SSNRIs), monoamine oxidase inhibitors (MAOIs), lithium, St. John's Wort, tryptophan supplements; and sibutramine (for weight loss), tramadol (a painkiller), pethidine (also a painkiller), linezolid (an antibiotic).

Care needs to be taken when* Dexinor XR i*s also used together with the following:

It is especially important if you are using one of the following:

- Alcohol
- Medicines containing ketoconazole (antifungal medicine)
- Tricyclic antidepressants
- Medicines containing codeine
- Sedatives such as midazolam
- Medicines used for schizophrenia such as aripiprazole
- Central nervous system active agents
- Medicines used for treating breast cancer such as tamoxifen and endoxifen
- Certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants e.g. warfarin, acetylsalicylic acid (e.g. Aspirin) and other non-steroidal anti-inflammatory drugs (e.g. ibuprofen).

False-positive

Due to the urine tests for drug testing being non-specific, a false-positive result for phencyclidine (PCP) and amphetamines may occur when using Dexinor XR

Dexinor XR with food, drink and alcohol

You may take your daily dose of Dexinor XR with or without food.

You should avoid drinking alcohol while you are using Dexinor XR

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 health care provider for advice before taking this medicine.

You must not use Dexinor XR if you are pregnant or breastfeeding.

It has not been proven that Dexinor XR is safe to use during pregnancy. If you are pregnant, or are planning to become pregnant, talk to your doctor before receiving Dexinor XR.

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

Dexinor XR passes into breast milk in humans. Ask your doctor for advice before breastfeeding your baby.

If Dexinor XR is used until, or shortly before birth, discontinuation effects in the newborn may occur.

Complications, including the need for respiratory support, tube feeding or prolonged hospitalisation, have been reported in neonates who are exposed to SNRIs or SSRIs late in the third trimester.

Driving and using machines

Dexinor XR may lower the ability to react quickly and appropriately enough to unexpected or

sudden events. Especially at the start of treatment and also if treatment is ended suddenly, you should allow for limitations in your capacity for judgement and reaction. Do not drive a car or other vehicle, do not operate any dangerous electrical tools or machines until you are sure that Dexinor XR does not impair your reaction capacity. Especially bear in mind that alcohol and other sedatives can additionally impair your reaction capacity.

3. How to take Dexinor XR

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

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

The recommended dose for Dexinor XR is 50 mg once daily, with or without food. Your doctor may increase the dose slowly at an interval of not less than 7 days, up to a maximum daily dose of 100 mg.

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

Your doctor will tell you how long your treatment with Dexinor XR will last. Do not stop treatment early. If you have the impression that the effect of Dexinor XR is too strong or too weak, tell your doctor or pharmacist.

Children:

Safety and effectiveness in children under 18 years of age has not been established.

Patients with kidney problems:

Care should be taken when treating patients with severe renal impairment and end stage renal disease with Dexinor XR. You should inform your doctor if you have or have had renal disease. Depending on the condition of your kidneys, your doctor may reduce the dose to avoid potential side effects. The reduction in kidney function should also be taken into consideration when you are elderly.

Use in elderly patients:

No dosage adjustment is required solely on the basis of age; however, possible reduced renal clearance of Dexinor XR should be considered when determining dose.

Patients with impaired liver function:

No dosage adjustment is necessary for patients with liver impairment.

If you take more Dexinor 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.

If you forget to take Dexinor XR

If you are concerned that you may have missed a dose, talk to your doctor or nurse immediately. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Dexinor XR

If your doctor decides treatment with Dexinor XR should be stopped, it will be done by gradually reducing the dose rather than abruptly stopping treatment so that the occurrence of withdrawal symptoms is minimised.

Switching from other antidepressants

If you are already using an antidepressant medicine prescribed by your doctor, you may experience side effects when discontinuing it in order to switch to Dexinor XR. Your doctor may gradually reduce the dose of your current antidepressant medication to help to reduce these side effects.

4. Possible side effects

Dexinor XR can have side effects.

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

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

- Allergic reaction with symptoms such as rash, itching, swelling of face or lips or tongue, difficulty breathing or swallowing
- Dizziness
- Sudden loss of consciousness with uncontrollable fit
- Abnormal bleeding or bruising
- Swelling or redness in or around the eye
- Stevens-Johnson syndrome (an extremely serious allergic skin reaction).

These are all very serious side effects. If you have them, you may have had a serious reaction to Dexinor 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 pain
- Angina
- Changes in the way your heart beats, for example, if you notice it beating faster
- Difficulty breathing
- Abnormal bleeding or bruising
- Swelling or redness in or around the eye
- Confusion, restlessness, sweating, shaking, hallucinations, sudden jerking of the muscles.

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 and/or irregular heartbeat, increased blood pressure
- Tinnitus (ringing or buzzing in ears)
- Blurred vision, mydriasis (dilation of pupils)
- Nausea, dry mouth, constipation, diarrhoea, vomiting
- Fatigue, chills, lack of energy, feeling jittery, irritability
- Weight gain, weight loss
- Decreased appetite
- Stiffness of the muscles and bones
- Dizziness, headache, sleepiness/sedation, tremor, paraesthesia (‘pins and needles’), taste loss, disturbance in attention
- Insomnia (sleeplessness), anxiety, abnormal dreams, nervousness, decreased sex drive, inability to orgasm
- Erectile dysfunction or failure, delayed ejaculation (male)
- Yawning
- Excessive sweating, rash
- Hot flushes.

Less frequent

- Allergic reaction
- Increased cholesterol, abnormal liver function tests, increased blood prolactin (prolactin is a hormone released by the pituitary gland that stimulates breast development and milk production)

- Low levels of sodium in the blood
- Syncope (fainting), convulsion, dystonia (sustained muscle contractions cause twisting and repetitive movements or abnormal postures), dyskinesia (impairment of voluntary movements resulting in fragmented or jerky motions)
- Withdrawal syndrome, abnormal orgasm, depersonalisation (feeling disconnected or detached from one's body and thoughts)
- Mania/hypomania (feeling overexcited, euphoric or overly irritable), hallucinations
- Difficulty starting or maintaining a urine stream, proteinuria
- Abnormal ejaculation (males), abnormal sexual function
- Epistaxis (nosebleeds)
- Alopecia (hair loss)
- Photosensitivity (sun allergy)
- Angioedema (swelling of the body usually due to an allergic reaction)
- Orthostatic hypotension (drop in blood pressure when standing up), especially in the elderly
- Cold hands and feet.

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 side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.By reporting side effects, you can help provide more information on the safety Dexinor XR.

5. How to store Dexinor XR

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use after the expiry date shown on the box.

Store in the original package.

Do not remove blister card from the carton until required for use.

Return all unused medicines 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 Dexinor XR contains

Dexinor XR:

The active substance is desvenlafaxine benzoate. Each extended-release tablet contains desvenlafaxine benzoate equivalent to 50 mg or 100 mg desvenlafaxine.

The other ingredients are cellulose microcrystalline, colloidal silicone dioxide, hypromellose, Opadry pink 85F94487 (50 mg only), Opadry pink 85F94527 (100 mg only), stearic acid and talc.

What Dexinor XR looks like and contents of the pack

Dexinor 50 XR:

Extended release tablets, light pink, biconvex, round shaped film coated tablets debossed with DV on one side and “50” on the other side.

Dexinor 100 XR:

Extended release tablets, reddish-orange, biconvex, round shaped film coated tablets, debossed with "DV" on one side and "100"on the other side.

Dexinor XR is packed in a blister with an aluminium foil lidding.

Dexinor XR extended release tablets are available in pack sizes of 30.

Holder of Certificate of registration

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