Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel

VEXINE
P1540309

VEXINE
P1540309

Berenice Campbell

Digitally signed by Berenice Campbell
DN: OU=Regulatory Affairs, O=Aurobindo Pharma (Pty) Ltd, CN=Berenice Campbell, E=berenice.campbell@aurobindo.com
Reason: I am the author of this document
Location: your signing location here
Date: 2026-04-20 15:22:44
Foxit PhantomPDF Version: 9.7.1

AUROGEN

Professional Information for Medicines for Human Use

SCHEDULING STATUS S5

1. NAME OF THE MEDICINE

VEXINE 37,5 mg
VEXINE 75 mg
VEXINE 150 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

VEXINE 37,5 mg:
Each extended release capsule contains venlafaxine hydrochloride equivalent to 37,5 mg venlafaxine
Contains sugar: 43,571 mg sucrose.

VEXINE 75 mg:
Each extended release capsule contains venlafaxine hydrochloride equivalent to 75 mg venlafaxine
Contains sugar: 87,142 mg sucrose.

VEXINE 150 mg:
Each extended release capsule contains venlafaxine hydrochloride equivalent to 150 mg venlafaxine
Contains sugar: 174,285 mg sucrose.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

VEXINE 37,5 mg
White to off white spherical to oval pellets filled in empty hard gelatin capsule shell (size '3') of opaque grey colour cap and opaque peach colour body imprinted with "E" on cap and "73" on the body with edible black ink.

VEXINE 75 mg
White to off white spherical to oval pellets filled in empty hard gelatin capsule shell (size '1') of opaque peach colour cap and opaque peach colour body imprinted with "E" on cap and "74" on the body with edible black ink.

VEXINE 150 mg
White to off white spherical to oval pellets filled in empty hard gelatin capsule shell (size '0') of opaque dark orange colour cap and opaque dark orange colour body imprinted with "E" on cap and "89" on the body with edible black ink.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

VEXINE is indicated for the treatment of depression, including depression with associated anxiety.

VEXINE is indicated for the prevention of relapses of an episode of depression in patients responding to an initial six to eight weeks of treatment. In patients responding to six months of relapse prevention, **VEXINE** may be used to prevent recurrence. Safety and efficacy beyond one year have not been demonstrated. When **VEXINE** is used for long-term it should periodically be re-evaluated for the usefulness of the product in the individual patient.

VEXINE is indicated for the treatment of generalised anxiety disorder and for the treatment of Social Anxiety Disorder.

The effectiveness of **VEXINE** in the treatment of Social Anxiety Disorder for more than 12 weeks has not been demonstrated.

4.2. Posology and method of administration

Posology
The usual recommended dose for **VEXINE** is 75 mg, given once daily. If after several weeks further clinical improvement is required, the dose may be increased to 150 mg, given once daily. If needed, the dose can be further increased up to 225 mg given once daily. Dose increments should be made at intervals of approximately 2 weeks or more, but not less than 4 days. The dose for depressed patients may be further increased, if needed, up to 375 mg, given once daily.

The extended-release formulation contains spheroids, which release the medicine slowly into the digestive tract. The insoluble portion of these spheroids is eliminated and may be seen in stools.

Special populations
Patients with renal impairment:
Patients with renal impairment should receive lower doses of **VEXINE**.

The total daily dose of **VEXINE** should be reduced by 25 – 50 % for patients with renal impairment with a glomerular filtration rate (GFR) of 10 – 70 mL/min.

The total daily dose of **VEXINE** should be reduced by 50 % in haemodialysis patients. Because of individual variability in clearance in these patients, individualisation of dosage may be desirable.

Patients with hepatic impairment:
The total daily dose of **VEXINE** should be reduced by 50 % in patients with mild to moderate hepatic impairment. Patients with severe hepatic impairment have not been studied; therefore, caution should be used if considering treating these patients with **VEXINE** and a further reduction should be considered.

Since there is a variability in clearance between hepatically impaired patients, individualisation of dosing, including further dose reductions (> 50 %), may be desirable in some patients. Because of individual variability in clearance in these patients, individualisation of dosage may be desirable.

Elderly patients:
No specific dosage adjustments of **VEXINE** are recommended based on patient age.

Paediatric population:
The safety and efficacy of **VEXINE** in children under the age of 18 years has not been established.

Maintenance, continuation and extended treatment:
The need for long-term therapy with **VEXINE** must be periodically reassessed. Whether the dose of antidepressant needed to induce remission is identical to the dose needed to maintain and/or sustain euthymia is unknown.

Discontinuing VEXINE:
Dose tapering is recommended whenever possible when discontinuing **VEXINE** therapy. Tapering over at least a two-week period is recommended if **VEXINE** has been used for more than 6 weeks. In clinical trials with venlafaxine extended-release capsules, tapering was achieved by reducing the daily dose by 75 mg at 1 - week intervals. The period required for tapering may depend on the dose, duration of therapy and the individual patient. Patients should be advised to consult their doctor before abruptly discontinuing **VEXINE** (see section 4.4).

Method of administration
It is recommended that **VEXINE** be taken with food. Each capsule should be swallowed whole with fluid. Do not divide, crush, chew or place capsule in water.

VEXINE should be administered once daily, at approximately the same time either in the morning or in the evening.

4.3. Contraindications

VEXINE is contraindicated:
- In patients with hypersensitivity to venlafaxine or to any excipients in **VEXINE** (see section 6.1)
- Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs)
- For at least 14 days after discontinuation of treatment with a MAOI
- And must be discontinued for at least 7 days before starting treatment with any MAOI (see section 4.5). Severe adverse reactions have been reported when **VEXINE** therapy is initiated soon after discontinuation of an MAOI and when an MAOI is initiated soon after discontinuation of **VEXINE**. These reactions have included tremor, myoclonus, diaphoresis, nausea, vomiting, flushing, dizziness, hyperthermia with features resembling neuroleptic malignant syndrome, seizures and death
- Children under 18 years (see section 4.4)
- Pregnancy and lactation (see section 4.6).

4.4. Special warnings and precautions for use

Suicide/suicidal thoughts or clinical worsening
Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). This risk persists until significant remission occurs. As improvements may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery.

Other psychiatric conditions for which venlafaxine is prescribed can also be associated with an increased risk of suicide-related events. In addition, these conditions may be co-morbid with major depressive disorder. The same precautions observed when treating patients with major depressive disorder should therefore be observed when treating patients with other psychiatric disorders.

Patients with a history of suicide-related events, or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment. A meta-analysis of placebo-controlled clinical trials of antidepressant drugs in adult patients with psychiatric disorders showed an increased risk of suicidal behaviour with antidepressants compared to placebo in patients less than 25 years old.

Close supervision of patients and in particular those at high risk should accompany therapy with **VEXINE** especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted about the need to monitor for any clinical worsening, suicidal behaviours or thoughts and unusual changes in behaviour, including anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restless), hypomania and mania, and to seek medical advice immediately if these symptoms present.

The smallest quantity of medicine, consistent with good patient management, should be provided to reduce the risk of overdose.

Use in children and adolescents under 18 years of age
VEXINE should not be used in the treatment of children and adolescents under the age of 18 years. (see section 4.3).

Serotonin syndrome
As with other serotonergic medicines, the development of a potentially life-threatening serotonin-syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions, may occur with venlafaxine treatment, particularly with concomitant use of other serotonergic medicines (including Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin-norepinephrine Reuptake Inhibitors (SNRIs) and triptans), with medicines that impair metabolism of serotonin such as MAO-inhibitors, or with antipsychotics or other dopamine antagonists (see section 4.5).

Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, and hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, and diarrhoea). Serotonin syndrome in its most severe form, can resemble NMS, which includes hyperthermia, muscle rigidity, autonomic instability with possible rapid fluctuation of vital signs and mental status changes.

If concomitant treatment with venlafaxine and other medicines that may affect the serotonergic and/or dopaminergic neurotransmitter systems is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases.

The concomitant use of venlafaxine with serotonin precursors (such as tryptophan supplements) is not recommended.

Narrow-angle glaucoma
Mydriasis may occur in association with venlafaxine. It is recommended that patients with raised intraocular pressure or patients at risk for acute narrow-angle glaucoma (angle-closure glaucoma) be closely monitored.

Blood pressure
Dose-related increases in blood pressure have been commonly reported with venlafaxine. In some cases, severely elevated blood pressure requiring immediate treatment has been reported in post marketing experience. All patients should be carefully screened for high blood pressure and pre-existing hypertension should be controlled before initiation of treatment. Blood pressure should be reviewed periodically, after initiation of treatment and after dose increases.

Caution should be exercised in patients whose underlying conditions might be compromised by increases in blood pressure, e.g., those with impaired cardiac function.

Heart rate
Increases in heart rate can occur, particularly with higher doses. Caution should be exercised in patients whose underlying conditions might be compromised by increases in heart rate.

Cardiac disease and risk of dysrhythmias
Venlafaxine has not been evaluated in patients with a recent history of myocardial infarction or unstable heart disease.

Therefore, it should be used with caution in these patients.

In post marketing experience, cases of QTc prolongation, Torsades de Pointes, ventricular tachycardia and fatal cardiac dysrhythmias have been reported with the use of venlafaxine, especially in overdose and in patients with other risk factors. The balance of risks and benefits should be considered before prescribing venlafaxine to patients at high risk of serious cardiac dysrhythmias or QTc prolongation.

Convulsions
Convulsions may occur with venlafaxine therapy. As with all antidepressants, venlafaxine should be introduced with caution in patients with a history of convulsions, and concerned patients should be closely monitored. Treatment should be discontinued in any patient who develops seizures.

Hyponatraemia
Cases of hyponatraemia and/or the Syndrome of Inappropriate Antidiuretic Hormone (SIADH) secretion may occur with venlafaxine. This has most frequently been reported in volume-depleted or dehydrated patients. Elderly patients, patients taking diuretics, and patients who are otherwise volume-depleted may be at greater risk for this event.

Abnormal bleeding
Medicines that inhibit serotonin uptake may lead to reduced platelet function. The risk of skin and mucous membrane bleeding, including gastrointestinal haemorrhage, may be increased in patients taking venlafaxine. As with other serotonin-reuptake inhibitors, venlafaxine should be used cautiously in patients predisposed to bleeding, including patients on anticoagulants and platelet inhibitors.

Serum cholesterol
Clinically relevant increases in serum cholesterol were recorded in 5,3 % of venlafaxine-treated patients and 0,0 % of placebo-treated patients treated for at least 3 months in placebo-controlled clinical trials. Measurement of serum cholesterol levels should be considered during long-term treatment.

Co-administration with weight loss agents
The safety and efficacy of venlafaxine therapy in combination with weight loss medicines, including phentermine, have not been established. Co-administration of venlafaxine and weight loss medicines is not recommended. Venlafaxine is not indicated for weight loss alone or in combination with other products.

Mania/hypomania
Mania/hypomania may occur in a small proportion of patients with mood disorders who have received antidepressants, including venlafaxine. As with other antidepressants, venlafaxine should be used cautiously in patients with a history or family history of bipolar disorder.

Aggression
Aggression may occur in a small number of patients who have received antidepressants, including venlafaxine. This has been reported under initiation, dose changes and discontinuation of treatment.
As with other antidepressants, venlafaxine should be used cautiously in patients with a history of aggression.

Discontinuation of treatment
Withdrawal symptoms, when treatment is discontinued, are common, particularly if discontinuation is abrupt (see section 4.8). In clinical trials, adverse events seen on treatment discontinuation (tapering and post-tapering) occurred in approximately 31 % of patients treated with venlafaxine and 17 % of patients taking placebo.

The risk of withdrawal symptoms may be dependent on several factors, including the duration and dose of therapy and the rate of dose reduction. Dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor and headache are the most commonly reported reactions. Generally, these symptoms are mild to moderate; however, in some patients they may be severe in intensity. They usually occur within the first few days of discontinuing treatment, but there have been very rare reports of such symptoms in patients who have inadvertently missed a dose. Generally, these symptoms are self-limiting and usually resolve within 2 weeks, though in some individuals they may be prolonged (2 - 3 months or more).

It is therefore advised that venlafaxine should be gradually tapered when discontinuing treatment over a period of several weeks or months, according to the patient's needs (see section 4.2).

Akathisia/psychomotor restlessness
The use of venlafaxine has been associated with the development of akathisia, characterised by a subjectively unpleasant or distressing restlessness and need to move often accompanied by an inability to sit or stand still. This is most likely to occur within the first few weeks of treatment. In patients who develop these symptoms, increasing the dose may be detrimental.

Dry mouth
Dry mouth is reported in 10 % of patients treated with venlafaxine. This may increase the risk of caries, and patients should be advised upon the importance of dental hygiene.

Diabetes
In patients with diabetes, treatment with an SSRI or venlafaxine may alter glycaemic control. Insulin and/or oral antidiabetic dosage may need to be adjusted.

Drug-Laboratory Test Interactions
False-positive urine immunoassay screening tests for phencyclidine (PCP) and amphetamine have been reported in patients taking venlafaxine. This is due to lack of specificity of the screening tests. False positive test results may be expected for several days following discontinuation of venlafaxine therapy. Confirmatory tests, such as gas chromatography/mass spectrometry, will distinguish venlafaxine from PCP and amphetamine.

Sucrose
VEXINE contains sugar spheres, containing sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take **VEXINE**.

4.5. Interaction with other medicines and other forms of interaction

Monoamine Oxidase Inhibitors (MAOI)
Venlafaxine must not be used in combination with MAOIs. Venlafaxine must not be initiated for at least 14 days after discontinuation of treatment with a MAOI. Venlafaxine must be discontinued for at least 7 days before starting treatment with an irreversible non-selective MAOI (see sections 4.3 and 4.4).

MAO inhibitor (moclobemide) and linezolid:
Due to the risk of serotonin syndrome, the combination of venlafaxine with a MAOI, such as moclobemide, is not recommended.

Serotonin syndrome
As with other serotonergic medicines, serotonin syndrome, a potentially life threatening condition, may occur with venlafaxine treatment, particularly with concomitant use of other medicines that may affect the serotonergic neurotransmitter system [including triptans, SSRIs, SNRIs, lithium, sibutramine, tramadol, or St. John's Wort (Hypericum perforatum)]. with medicines which impair metabolism of serotonin (including MAOIs), or with serotonin precursors (such as tryptophan supplements). (see section 4.3).

If concomitant treatment of venlafaxine with an SSRI, an SNRI or a serotonin receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases. The concomitant use of venlafaxine with serotonin precursors (such as tryptophan supplements) is not recommended (see section 4.4).

CNS-active substances
The risk of using venlafaxine in combination with other CNS-active substances has not been systematically evaluated. Consequently, caution is advised when venlafaxine is taken in combination with other CNS-active substances.

Ethanol
Venlafaxine has been shown not to increase the impairment of mental and motor skills caused by ethanol. However, as with all CNS-active substances, patients should be advised to avoid alcohol consumption.

Drugs that Prolong the QT Interval
The risk of QTc prolongation and/or ventricular dysrhythmias (e.g., TdP) is increased with concomitant use of other medicines which prolong the QTc interval. Co-administration of such medicines should be avoided (see section 4.4).
Relevant classes include:
- class Ia and III antiarrhythmics (e.g. quinidine, amiodarone, sotalol, dofetilide)
- some antipsychotics (e.g. thioridazine)
- some macrolides (e.g. erythromycin)
- some antihistamines
- some quinolone antibiotics (e.g. moxifloxacin).

The above list is not exhaustive and other individual medicines known to significantly increase QT interval should be avoided.

Effect of other medicines on venlafaxine
Ketoconazole (CYP3A4 inhibitor)
A pharmacokinetic study with ketoconazole in CYP2D6 extensive (EM) and poor metabolisers (PM) resulted in higher concentrations of venlafaxine and O-desmethylvenlafaxine (ODV) following administration of ketoconazole. Concomitant use of CYP3A4 inhibitors (e.g., atazanavir, clarithromycin, indinavir, itraconazole, voriconazole, posaconazole, ketoconazole, nelfinavir, ritonavir, saquinavir, telithromycin) and venlafaxine may increase levels of venlafaxine and ODV. Therefore, caution is advised if a patient's therapy includes a CYP3A4 inhibitor and venlafaxine concomitantly.

Effect of venlafaxine on other medicines
Medicines metabolized by Cytochrome P450 Isoenzymes
In vivo studies indicate that venlafaxine is a relatively weak inhibitor of CYP2D6. Venlafaxine did not inhibit CYP3A4 (alprazolam and carbamazepine), CYP1A2 (caffeine), and CYP2C9 (tolbutamide) or CYP2C19 (diazepam) *in vivo*.

Lithium
Serotonin syndrome may occur with the concomitant use of venlafaxine and lithium (see Serotonin syndrome).

Diazepam
Venlafaxine has no effects on the pharmacokinetics and pharmacodynamics of diazepam and its active metabolite, desmethyldiazepam. Diazepam does not appear to affect the pharmacokinetics of either venlafaxine or ODV. It is unknown whether a pharmacokinetic and/or pharmacodynamic interaction with other benzodiazepines exists.

Imipramine
Venlafaxine did not affect the pharmacokinetics of imipramine and 2-OH-imipramine. There was a dose-dependent increase of 2-OH-desipramine AUC by 2,5 to 4,5-fold when venlafaxine 75 mg to 150 mg daily was administered. Imipramine did not affect the pharmacokinetics of venlafaxine and ODV. The clinical significance of this interaction is unknown. Caution should be exercised with co-administration of venlafaxine and imipramine.

Haloperidol
A pharmacokinetic study with haloperidol has shown a 42 % decrease in total oral clearance, a 70 % increase in AUC, an 88 % increase in C_{max}, but no change in half-life for haloperidol. This should be taken into account in patients treated with haloperidol and venlafaxine concomitantly. The clinical significance of this interaction is unknown.

Risperidone
Venlafaxine increased the risperidone AUC by 50 %, but did not significantly alter the pharmacokinetic profile of the total active moiety (risperidone plus 9-hydroxyrisperidone). The clinical significance of this interaction is unknown.

Metoprolol
Concomitant administration of venlafaxine and metoprolol to healthy volunteers in a pharmacokinetic interaction study for both medicines resulted in an increase of plasma concentrations of metoprolol by approximately 30 - 40 % without altering the plasma concentrations of its active metabolite, α-hydroxymetoprolol. The clinical relevance of this finding in hypertensive patients is unknown. Metoprolol did not alter the pharmacokinetic profile of venlafaxine or its active metabolite, ODV. Caution should be exercised with co-administration of venlafaxine and metoprolol.

Indinavir
A pharmacokinetic study with indinavir has shown a 28 % decrease in AUC and a 36 % decrease in C_{max} for indinavir. Indinavir did not affect the pharmacokinetics of venlafaxine and ODV. The clinical significance of this interaction is unknown.

4.6. Fertility, pregnancy and lactation

Pregnancy
VEXINE must not be administered to pregnant or lactating women. Safety during human pregnancy and lactation has not been established (see section 4.3). Some neonates exposed to **VEXINE** late in the third trimester have developed complications requiring tube feeding, respiratory support or prolonged hospitalisation. Such complications can arise immediately upon delivery.

Patients should be advised to notify their doctor if they become pregnant or intend to become pregnant during therapy.

Lactation
Venlafaxine and ODV are excreted in human milk; therefore, mothers on treatment with **VEXINE** should not breastfeed.

DETACH BEFORE DISPENSING

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

VEXINE
Contains sugar:
VEXINE 37,5 mg: 43,571 mg sucrose
VEXINE 75 mg: 87,142 mg sucrose
VEXINE 150 mg: 174,285 mg sucrose

Read all of this leaflet carefully before you start taking VEXINE
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **VEXINE** 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 **VEXINE** is and what it is used for
2. What you need to know before you use **VEXINE**
3. How to use **VEXINE**
4. Possible side effects
5. How to store **VEXINE**
6. Contents of the pack and other information

1. What VEXINE is and what it is used for

VEXINE is indicated for the treatment of depression (a mental health disorder characterised by persistently depressed mood or loss of interest in activities, causing significant impairment in daily life), including depression with associated anxiety.

VEXINE is indicated for the prevention of relapses of an episode of depression in patients responding to an initial six to eight weeks of treatment. In patients responding to six months of relapse prevention, **VEXINE** may be used to prevent recurrence. Safety and efficacy beyond one year have not been demonstrated. When **VEXINE** is used for long-term it should occasionally be re-evaluated for the usefulness of the product in the individual patient.

VEXINE is indicated for the treatment of severe, ongoing anxiety that interferes with daily activities (generalised anxiety disorder) and for the treatment of A chronic mental health condition in which social interactions cause irrational anxiety (Social Anxiety Disorder).

The effectiveness of **VEXINE** in the treatment of Social Anxiety Disorder for more than 12 weeks has not been demonstrated.

2. What you need to know before you take VEXINE

Do not take VEXINE:
- If you are hypersensitive (allergic) to venlafaxine or any of the ingredients of **VEXINE**. (listed in section 6)
- If you are less than 18 years of age
- If you are taking or have recently taken (within the last two weeks) another antidepressant drug known as a monoamine oxidase inhibitor (MAOI)
- If you are pregnant or breastfeeding.

Take special care with VEXINE and tell your doctor
- If you experience worsening of your depression, or if you have suicidal thoughts or behaviour. You should contact your doctor immediately
- If you experience symptoms of neuroleptic malignant syndrome which include high fever, muscle stiffness, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, rapid heartbeat, excessive sweating and abnormal heart beat)
- If you have eye problems or suffer from, or have a history of, glaucoma
- If you experience increase in blood pressure or increased heart rate
- If you have heart problems
- If you experience convulsions (a sudden, violent, irregular movement of the body, caused by involuntary contraction of muscles)
- If you are taking diuretic medications (medication which increases the excretion of water and salt from the body). as this may result in hyponatraemia (a condition that occurs when the level of sodium in the blood is too low), when taken together with **VEXINE**
- If you are prone to bruising or bleed easily or if you are taking medicines that increase your risk of bleeding
- If you have a history or family history of bipolar disorder (a disorder associated with episodes of mood swings ranging from depressive lows to manic high)
- If you have a history of aggression
- If you experience a feeling of muscle quivering, restlessness and inability to sit still
- If you have diabetes
- **VEXINE** can cause dry mouth, therefore it is important to maintain good dental hygiene.

Taking other medicines with VEXINE:
Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines). See Do not take **VEXINE**.
Tell your doctor if you are taking or using any of the following medicines:
- Monoamine Oxidase Inhibitors (MAOI) (used to treat depression or Parkinson's disease)
- Selective serotonin reuptake inhibitors (SSRIs) or lithium
- Central Nervous system stimulating substances (quinidine, amiodarone, sotalol, dofetilide)
- some antipsychotics (e.g. thioridazine)
- some macrolides (e.g. erythromycin)
- some antihistamines
- some quinolone antibiotics (e.g. moxifloxacin)
- Certain medicines can affect the way **VEXINE** passes through your body (atazanavir, clarithromycin, indinavir, itraconazole, voriconazole, posaconazole, ketoconazole, nelfinavir, ritonavir, saquinavir and telithromycin)
- **VEXINE** can affect the way certain medicines pass through the body (lithium, diazepam, imipramine, haloperidol, risperidone, metoprolol and indinavir).
- Weight loss medicines (taking weight loss medicines with **VEXINE** is not recommended **VEXINE** with food, drink and alcohol

VEXINE with food, drink and alcohol:
You should avoid alcohol while taking **VEXINE**.

Pregnancy, breastfeeding and fertility
You should not use **VEXINE** if you are pregnant.

VEXINE is excreted in human milk. Patients should be advised not to breast feed if they are taking **VEXINE**.

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 professional for advice before taking **VEXINE.**

Driving and using machines
VEXINE may impair your judgment, thinking, and motor skills. Therefore, caution should be observed when operating hazardous machines, including motor vehicles, until you are reasonably certain that venlafaxine does not affect you adversely

Important information about some of the ingredients of VEXINE
VEXINE contains lactose monohydrate, it is a sugar. So before taking **VEXINE**, please consult your doctor for advice if you have an intolerance to lactose monohydrate.

3. How to take VEXINE

Do not share medicines prescribed for you with any other person. Always take **VEXINE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with **VEXINE** will last.

VEXINE should be swallowed whole with fluid. Do not divide, crush, chew or place capsule in water.

VEXINE should be administered once daily, at approximately the same time either in the morning or in the evening.

Take **VEXINE** with food.

The usual recommended dose for **VEXINE** is 75 mg, given once daily. If required, your doctor may increase the dose to 150 mg, given once daily. If needed, the dose can be further increased up to 225 mg given once daily.

Dose increases have to be done gradually and your doctor will explain how to do this.

The extended-release formulation contains spheroids, which release the medicine slowly into the digestive tract. The insoluble portion of these spheroids is eliminated and may be seen in stools.

If you take more VEXINE than you should
In the event of over dosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.
Overdose with **VEXINE** was mainly reported with concomitant use of alcohol and/or other medicines (see other medicines and **VEXINE**).
The symptoms of a possible overdose may include a rapid or slow heartbeat, changes in the electrical activity of your heart which may be seen in tests, low blood pressure, low blood sugar, dizziness, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures (fits), vomiting and death.

If you missed a dose of VEXINE
If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

VEXINE can have side effects.

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

If any of the following happens, stop taking **VEXINE** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swollen face or tongue, or shortness of breath or difficulty breathing, often with skin rashes (this may be a serious allergic reaction)
- Seizures, fits or convulsions
- Rapid or irregular heartbeat, flushing or fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **VEXINE**. 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:
- Severe muscle tenderness, stiffness or weakness, especially if accompanied by dark urine (this can be caused by muscle breakdown leading to kidney problems – 'rhabdomyolysis')
- Severe abdominal or back pains (which could indicate a serious problem in the gut, liver or pancreas)
- A high temperature with rigid muscles, confusion or agitation, and sweating or if you experience jerky muscle movements which you can't control. These may be symptoms of a serious conditions known as neuroleptic malignant syndrome
- Euphoric feelings, drowsiness, sustained rapid eye movement, clumsiness, restlessness, feeling of being drunk, sweating or rigid muscles, which are symptoms of serotonergic syndrome
- Frequent or unusual bruising or bleeding, such as nose bleeds (this could indicate that **VEXINE** has had an effect on your blood, and this may need to be tested)
- Feeling 'high' or very over-excited (mania or hypomania).

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
- Headache, unusual tiredness or weakness, sweating, dizziness, dry mouth, difficulty sleeping or drowsiness, nervousness
- Change in sexual function e.g. abnormal ejaculation in men, lack of orgasm
- Change in appetite or bowel habits, diarrhoea or constipation, abdominal discomfort, vomiting, indigestion, weight loss or gain
- Persistent problems falling asleep (insomnia)
- Agitation, confusional state, abnormal dreams
- Feeling of restlessness or if you feel unable to sit or stand still
- Altered taste sensation
- Visual impairment, unable to focus eyes, especially on nearby objects, vision blurred, dilation of pupils
- Tinnitus (ringing of the ear)
- Increased heart beat or feelings that your heart is pounding.
- High blood pressure and hot flush
- Difficulty in breathing (dyspnoea) or yawning
- Excessive sweating, including night sweats
- Rash and itchiness
- Increased tightness of muscle tone and reduced capacity of the muscle to stretch
- Feeling the need to go to the toilet more often than usual or difficulty in urinating
- Menstrual disturbances in women
- Fatigue, abnormal physical weakness, chills
- Blood cholesterol increased (your doctor will run a blood test to determine this).

Less frequent side effects:
- Inappropriate vasopressin (control blood pressure) hormone secretion
- Blood prolactin increased resulting in abnormal breast milk production
- A condition that occurs when the level of sodium in the blood is too low (condition known as hyponatraemia whereby the body holds onto too much water)
- Feeling 'high' or very over-excited (condition known as mania, hypomania)
- Disorientation and confusion often accompanied by hallucination (condition known as delirium)
- Abnormal orgasm
- Lack of interest, enthusiasm, or concern
- Clenching or grinding of teeth, muscle spasm
- Suicidal ideation and suicidal behaviours
- Feeling aggressive or having aggressive thoughts
- Fainting or a sudden temporary loss of consciousness (condition known as syncope)
- A sudden, involuntary muscle jerk, shake or spasm (condition known as myoclonus)
- Balance disorder, abnormality or impairment of voluntary movement (condition known as dyskinaesia)
- Involuntary muscle contractions that cause repetitive or twisting movements (condition known as dystonia)
- Raise in eye pressure (condition known as angle closure glaucoma)
- Stiff, jerky movements of your face and body that you can't control (condition known as tardive dyskinaesia)
- Sense of spinning dizziness (condition known as vertigo)
- Abnormal heart rhythm, fast heart rate, erratic heart rate,
- Feeling dizzy or unsteady on standing due to a fall in blood pressure (especially for elderly patients)
- All forms of bleeding in the gastrointestinal tract, from the mouth to the rectum (conditions known as gastrointestinal haemorrhage)
- Yellow coloration of the skin and eyes,
- Hives, hair loss, a discoloration of the skin resulting from bleeding underneath, typically caused by bruising
- Painless swelling under the skin
- Increased sensitivity of your skin to sunlight
- A rare, serious disorder of your skin and mucous membranes. It's usually a reaction to a medication or an infection. Often, it begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters (condition known as Stevens-Johnson syndrome)
- A potentially life-threatening dermatologic disorder characterized by widespread erythema and necrosis (condition known as toxic epidermal necrolysis)
- A skin disorder characterised by bull's-eye-shaped lesions. (condition known as erythema multiforme)
- Loss of bladder control
- Bleeding time prolonged
- Abnormalities of the blood which your doctor will determine by doing a blood test.

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 via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of **VEXINE.**

5. How to store VEXINE

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Store at or below 25 °C.
- Keep in original packaging until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- 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 VEXINE contains
The active substance is venlafaxine.

VEXINE 37,5 mg:
Each extended release capsule contains venlafaxine hydrochloride equivalent to 37,5 mg venlafaxine.
Contains sugar: 43,571 mg sucrose.

VEXINE 75 mg:
Each extended release capsule contains venlafaxine hydrochloride equivalent to 75 mg venlafaxine.
Contains sugar: 87,142 mg sucrose.

VEXINE 150 mg:
Each extended release capsule contains venlafaxine hydrochloride equivalent to 150 mg venlafaxine.
Contains sugar: 174,285 mg sucrose.

The other ingredients are ethyl cellulose, hypromellose, methanol, methylene chloride, sugar spheres.

Composition of capsule shell:
Gelatin, iron oxide black (C.I No. 77499), iron oxide red (C.I. No. 77491), sodium lauryl sulphate, titanium dioxide (C.I. No. 77891).

Composition of ink:
Black iron oxide (C.I. No. 77499), butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonia solution.

What VEXINE looks like and contents of the pack
VEXINE 37,5 mg
White to off white spherical to oval pellets filled in empty hard gelatin capsule shell (size '3') of opaque grey colour cap and opaque peach colour body imprinted with "E" on cap and "73" on the body with edible black ink.

VEXINE 75 mg
White to off white spherical to oval pellets filled in empty hard gelatin capsule shell (size '1') of opaque peach colour cap and opaque peach colour body imprinted with "E" on cap and "74" on the body with edible black ink.

VEXINE 150 mg
White to off white spherical to oval pellets filled in empty hard gelatin capsule shell (size 0) of opaque dark orange colour cap and opaque dark orange colour body imprinted with "E" on cap and "89" on the body with edible black ink.

Blister pack:
30 capsules are packed in micron PVC/25 micron PE/90 gsm PVdc Film - Aluminium foil blister pack.
Each carton contains 3 blisters of 10 capsules each. The blisters are further packed in preprinted cartons with a leaflet.

Pack size: 30s - Each carton contains 3 blisters of 10 capsules each.

Holder of Certificate of Registration
Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa
Tel.no.: +27 11 867 9100

This leaflet was last revised in:
20 March 2026

REGISTRATION NUMBER:
VEXINE 37,5 mg: 47/1.2/0080
VEXINE 75 mg: 47/1.2/0081
VEXINE 150 mg: 47/1.2/0082

4.7. Effects on ability to drive and use machines
VEXINE may cause dizziness, sedation and visual disturbances.
Therefore, any patient receiving venlafaxine should be cautioned about their ability to drive or operate hazardous machinery.

4.8. Undesirable effects
a. ***Summary of the safety profile***
The most frequently reported adverse reactions in clinical studies were nausea, dry mouth, headache and sweating (including night sweats).

b. ***Tabulated list of adverse reactions***

SYSTEM ORGAN CLASS	FREQUENCY
Blood and lymphatic system disorders	
Agranulocytosis* Aplastic anaemia Pancytopaenia* Neutropaenia* Thrombocytopaenia*	Less frequent
Immune system disorders	
Anaphylactic reaction*	Less frequent
Endocrine disorders	
Inappropriate antidiuretic hormone secretion* Blood prolactin increased*	Less Frequent
Metabolism and nutrition disorders	
Decreased appetite Hyponatraemia*	Frequent Less frequent
Psychiatric disorders	
Insomnia Confusional state* Depersonalization* Abnormal dreams Nervousness Libido decreased Agitation* Anorgasmia	Frequent
Mania Hypomania Hallucination Derealization Abnormal orgasm Bruxism* Apathy Delirium*	Less frequent
Suicidal ideation and suicidal behaviours[a] Aggression[b]	Frequency not known
Nervous system disorders	
Headache*[c] Dizziness Akathisia* Tremor Paraesthesia Sedation Dysgeusia	Frequent
Syncope Myoclonus Balance disorder* Coordination abnormal* Dyskinaesia* Neuroleptic Malignant Syndrome (NMS)* Serotonin syndrome* Convulsion Dystonia* Tardive Dyskinaesia*	Frequent
Tardive Dyskinaesia	Less frequent
Eye disorders	
Visual impairment Accommodation disorder Including vision blurred Mydriasis	Frequent
Angle-closure glaucoma*	Less frequent
Ear and labyrinth disorders	
Tinnitus*	Frequent
Vertigo	Frequency not known
Cardiac disorders	
Tachycardia Palpitations*	Frequent
Torsade de pointes* Ventricular tachycardia* Ventricular fibrillation Electrocardiogram QT prolonged*	Less Frequent
Vascular disorders	
Hypertension Hot flush	Frequent
Orthostatic hypotension Hypotension*	Frequent
Respiratory, thoracic and mediastinal disorders	
Dyspnoea* Yawning	Frequent
Interstitial lung disease* Pulmonary eosinophilia*	Less Frequent
Gastrointestinal disorders	
Nausea Dry mouth Constipation Diarrhoea* Vomiting	Frequent
Gastrointestinal haemorrhage* Pancreatitis*	Frequent Less frequent
Hepatobiliary disorders	
Liver function test abnormal* Hepatitis*	Frequent Less Frequent
Skin and subcutaneous tissue disorders	
Hyperhidrosis (including night sweats)* Rash Pruritus*	Frequent
Urticaria* Alopecia* Ecchymosis Angioedema* Photosensitivity reaction Stevens-Johnson syndrome* Toxic epidermal necrolysis* Erythema multiforme	Less frequent
Musculoskeletal and connective tissue disorders	
Hypertonia	Frequent
Rhabdomyolysis*	Less Frequent
Renal and urinary disorders	
Urinary hesitation Urinary retention Pollakiuria*	Frequent
Urinary incontinence*	Less frequent
Reproductive system and breast disorders	
Menorrhagia* Metrorrhagia* Erectile dysfunctionb Ejaculation disorderb	Frequent
General disorders and administration site conditions	
Fatigue Asthenia Chills* Mucosal haemorrhage*	Frequent
Mucosal haemorrhage	Frequency not known
Investigations	
Weight decreased Weight increased Blood cholesterol increased	Frequent
Bleeding time prolonged*	Frequency not known

*ADR identified post-marketing.
a Cases of suicidal ideation and suicidal behaviours have been reported during venlafaxine therapy or early aftertreatment discontinuation (see section 4.4).
b See section 4.4.
c In pooled clinical trials, the incidence of headache with venlafaxine and placebo were similar.

c. Description of selected adverse reactions
Discontinuation of treatment
Discontinuation of venlafaxine (particularly when abrupt) commonly leads to withdrawal symptoms. Dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor, vertigo, headache and flu syndrome are the most commonly reported reactions. Generally, these events are mild to moderate and are self-limiting; however, in some patients, they may be severe and/or prolonged. It is therefore advised that when venlafaxine treatment is no longer required, gradual discontinuation by dose tapering should be carried out (see sections 4.2 and 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9. Overdose
Symptoms
In post-marketing experience, overdose with **VEXINE** was reported predominantly in combination with alcohol and/or other medicines. The most commonly reported events in overdose include tachycardia, changes in level of consciousness (ranging from somnolence to coma), mydriasis, convulsion and vomiting. Other events reported include electrocardiographic changes (e.g. prolongation of QT interval, bundle branch block, QRS prolongation), ventricular tachycardia, bradycardia, hypotension, hypoglycaemia, vertigo and death. Published retrospective studies report that **VEXINE** overdosage may be associated with an increased risk of fatal outcomes compared to that observed with SSRI antidepressant products, but lower than that for tricyclic antidepressants. Epidemiological studies have shown that **VEXINE** treated patients have a higher burden of suicide risk factors than SSRI patients. The extent to which the finding of an increased risk of fatal outcomes can be attributed to the toxicity of **VEXINE** in overdosage as opposed to some characteristics of **VEXINE** - treated patients is not clear. Prescriptions for **VEXINE** should be written for the smallest quantity of medicine consistent with good patient management, in order to reduce the risk of overdose.

Treatment
General supportive and symptomatic measures are recommended; cardiac rhythm and vital signs must be monitored. When there is a risk of aspiration, induction of emesis is not recommended.
Administration of activated charcoal may also limit medicine absorption.

Forced diuresis, dialysis, haemoperfusion and exchange transfusion are unlikely to be of benefit. No specific antidotes for **VEXINE** are known.

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic properties
Other antipsychotics, ATC code: N06AX16

Mechanism of action
The mechanism of venlafaxine's antidepressant action in humans is believed to be associated with its potentiation of neurotransmitter activity in the central nervous system. Preclinical studies have shown that venlafaxine and its major metabolite, ODV, are inhibitors of serotonin and noradrenaline reuptake. Venlafaxine also weakly inhibits dopamine uptake. Venlafaxine and its active metabolite reduce β adrenergic responsiveness after both acute (single dose) and chronic administration. Venlafaxine and ODV are very similar with respect to their overall action on neurotransmitter reuptake and receptor binding.

Venlafaxine has virtually no affinity for rat brain muscarinic, cholinergic, H_1-histaminergic or α_1 adrenergic receptors in vitro. Pharmacological activity at these receptors may be related to various side effects seen with other antidepressant medicinal products, such as anticholinergic, sedative and cardiovascular side effects.

Venlafaxine does not possess monoamine oxidase (MAO) inhibitory activity.

In vitro studies revealed that venlafaxine has virtually no affinity for opiate or benzodiazepine sensitive receptors.

5.2. Pharmacokinetic properties
Venlafaxine is extensively metabolised, primarily to the active metabolite, ODV. Mean ± SD plasma half-lives of venlafaxine and ODV are 5 ± 2 hours and 11 ± 2 hours, respectively.

Absorption
At least 92 % of venlafaxine is absorbed following single oral doses of immediate-release venlafaxine. Absolute bioavailability is 40 % to 45 % due to presystemic metabolism. After immediate-release venlafaxine administration, the peak plasma concentrations of venlafaxine and ODV occur in 2 and 3 hours, respectively. Following the administration of venlafaxine prolonged-release capsules, peak plasma concentrations of venlafaxine and ODV are attained within 5,5 hours and 9 hours, respectively. When equal daily doses of venlafaxine are administered as either an immediate-release tablet or prolonged release capsule, the prolonged-release capsule provides a slower rate of absorption, but the same extent of absorption compared with the immediate-release tablet. Food does not affect the bioavailability of venlafaxine and ODV.

Distribution
Venlafaxine and ODV are minimally bound at therapeutic concentrations to human plasma proteins (27 % and 30 %, respectively). The volume of distribution for venlafaxine at steady-state is 4,4 ± 1,6 L/kg following intravenous administration.

Biotransformation
Venlafaxine undergoes extensive hepatic metabolism. *In vitro* and *in vivo* studies indicate that venlafaxine is biotransformed to its major active metabolite, ODV, by CYP2D6. *In vitro* and *in vivo* studies indicate that venlafaxine is metabolised to a minor, less active metabolite, N-desmethylvenlafaxine, by CYP3A4. In vitro and *in vivo* studies indicate that venlafaxine is a weak inhibitor of CYP2D6. Venlafaxine did not inhibit CYP1A2, CYP2C9, or CYP3A4.

Elimination
Venlafaxine and its metabolites are excreted primarily through the kidneys. Approximately 87 % of a venlafaxine dose is recovered in the urine within 48 hours as either unchanged venlafaxine (5 %), unconjugated ODV (29 %), conjugated ODV (26 %), or other minor inactive metabolites (27 %). Mean ± SD plasma steady state clearances of venlafaxine and ODV are 1,3 ± 0,6 L/h/kg and 0,4 ± 0,2 L/h/kg, respectively.

Linearity
Steady-state concentrations of venlafaxine and ODV are attained within 3 days of oral multiple dose therapy. Venlafaxine and ODV exhibit linear kinetics over the dose range of 75 mg to 450 mg/day.

Special Populations
Elderly
A 20 % reduction in clearance was noted for ODV in subjects over 60 years old: The magnitude of the differences that were seen is insufficient to warrant dosage adjustment based solely on age.

Renal impairment
In patients with moderate to severe impairment of renal function, the total clearance of both venlafaxine and ODV was reduced, and t½ was prolonged. The reduction in total clearance was most pronounced in subjects with creatinine clearance less than 30 mL/min. Dosage adjustment is recommended for these patients (see section 4.2).

Hepatic impairment
In patients with compensated hepatic cirrhosis (mild to moderate hepatic impairment), the pharmacokinetic disposition of both venlafaxine and ODV was significantly altered.

The reduction in both the metabolism of venlafaxine and elimination of ODV resulted in significantly higher plasma concentrations of both. Dosage adjustment is recommended in these patients (see section 4.2).

Effects of food
Administration of venlafaxine with food has no effect on the extent of absorption of venlafaxine or on the subsequent formation of ODV.

Preclinical safety data
Studies with venlafaxine in rats and mice revealed no evidence of carcinogenesis. Venlafaxine was not mutagenic in a wide range of *in vitro* and *in vivo* tests.

6. PHARMACEUTICAL PARTICULARS
6.1. List of excipients
Ethyl cellulose, hypromellose, methanol, methylene chloride, sugar spheres.

Composition of capsule shell:
Gelatin, iron oxide black (C.I No. 77499), iron oxide red (C.I. No. 77491), sodium lauryl sulphate, titanium dioxide (C.I. No. 77891).

Composition of ink:
Black iron oxide (C.I. No. 77499), butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonia solution.

6.2. Incompatibilities
Not applicable

6.3. Shelf life
3 years

6.4. Special precautions for storage
Store at or below 25 °C.
Keep in original packaging until required for use.

6.5. Nature and contents of container
Blister pack:
30 capsules are packed in micron PVC/25 micron PE/90 gsm PVdc Film - aluminium foil blister pack.
Each carton contains 3 blisters of 10 capsules each. The blisters are further packed in preprinted cartons with a leaflet.

Pack size: 30's - Each carton contains 3 blisters of 10 capsules each.

6.6. Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa
Tel.no.: +27 11 867 9100

8. REGISTRATION NUMBER(S)
VEXINE 37,5 mg: 47/1.2/0080
VEXINE 75 mg: 47/1.2/0081
VEXINE 150 mg: 47/1.2/0082

9. DATE OF FIRST AUTHORISATION
22 June 2021

10. DATE OF REVISION OF THE TEXT
20 March 2026

P1540309

DETACH BEFORE DISPENSING

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S5

VEXINE
Venlafaksien
Bevat suiker:
VEXINE 37,5 mg: 43,571 mg sukrose
VEXINE 75 mg: 87,142 mg sukrose
VEXINE 150 mg: 174,285 mg sukrose

Lees hierdie inligtingsblad noukeurig deur voordat jy begin om VEXINE te neem
- Hou hierdie inligtingsblad. Dit mag nodig wees om dit weer te lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter of apteker.
- **VEXINE** is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit kan skadelik wees vir hulle, al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingsblad:
1. Wat is **VEXINE** en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy **VEXINE** neem
3. Hoe om **VEXINE** te neem
4. Moontlike newe-effekte
5. Hoe om **VEXINE** te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat is VEXINE en waarvoor word dit gebruik
VEXINE word aangedui vir die behandeling van depressie ('n geestesgesondheidversteuring gekenmerk deur volgehoue terneergedrukte gemoed of verlies aan belang in aktiwiteite, wat beduidende inkorting van daaglikse lewe veroorsaak), insluitende depressie met gepaardgaande angstigheid.

VEXINE word aangedui vir die voorkoming van terugvalle van 'n episode van depressie by pasiënte wat op 'n aanvanklike ses tot agt weke van behandeling reageer. By pasiënte wat reageer op ses maande van terugvalvoorkoming, kan **VEXINE** gebruik word om herhaling te voorkom. Veiligheid en doeltreffendheid van behandeling vir langer as een jaar is nie aangedui nie. Wanneer **VEXINE** oor die lang termyn gebruik word, moet die nut van die produk by die individuele pasiënt van tyd tot tyd geherevalueer word.

VEXINE word aangedui vir die behandeling van hewige, aanhoudende angstigheid wat inmeng met daaglikse aktiwiteite (algemene angssteuring) en vir die behandeling van 'n chroniese geestesgesondheidtoestand waar sosiale interaksies irrasionele angstigheid veroorsaak (sosiale angssteuring).

Die doeltreffendheid van **VEXINE** in die behandeling van sosiale angssteuring vir meer as 12 weke is nie aangedui nie.

2. Wat jy moet weet voordat jy VEXINE neem
Moenie VEXINE neem nie:
- Indien jy hipersensitief (allergies) vir venlafaksien of vir enige van die bestanddele van **VEXINE** is (gelys by afdeling 6)
- Indien jy jonger as 18-jarige ouderdom is
- Indien jy 'n ander antidepressant-medisyne bekend as 'n monoamienoksidase-inhibeerder (MAOI) neem of onlangs geneem het (binne die afgelope twee weke)
- Indien jy swanger is of borsvoed.

Neem spesiale sorg met VEXINE en lig jou dokter in
- Indien jy verergering van jou depressie ervaar, of indien jy selfdoodgedagtes of -gedrag ondervind. Kontak onmiddellik jou dokter.
- Indien jy simptome van neuroleptiese maligne sindroom ervaar, wat hoë koors, spierstyfheid, gewysigde geestestoestand en tekens van outonomiese onstabiliteit (onegalige pols of bloeddruk, vinnige hartklop, oormatige sweting en abnormale hartklop) insluit
- Indien jy oogprobleme het, of aan gloukoom ly of 'n geskiedenis daarvan het
- Indien jou bloeddruk verhoog of jou hartklop versnel
- Indien jy hartprobleme het
- Indien jy konvulsies ervaar (skielike, heftige, onreëlmatige bewegings van die liggaam, veroorsaak deur onwillekeurige spiersametrekkings).
- Indien jy diuretiese medisynes neem (medisyne wat die uitskeiding van water en sout uit die liggaam verhoog), aangesien dit hiponatremie ('n toestand wat voorkom as die natriumvlakke in die bloed te laag is) kan veroorsaak wanneer dit saam met **VEXINE** geneem word
- Indien jy geneig is om maklik te kneus of te bloei, of indien jy medisynes neem wat jou risiko van bloeding verhoog
- Indien jy 'n geskiedenis of familiegeskiedenis van bipolêre versteuring het ('n versteuring wat met episodes van wisselende buie van terneergedruktheid tot maniese uitgelatenheid gepaard gaan)
- Indien jy 'n geskiedenis van aggressiewe gedrag het
- Indien jy spiertrillings ervaar, rusteloosheid ondervind en voel of jy nie kan stilsit nie
- Indien jy aan diabetes ly
- **VEXINE** kan 'n baie droë mond veroorsaak, daarom is dit belangrik om goeie mondhigiëne te handhaaf.

Die neem van ander medisynes met VEXINE:
Sê altyd vir jou gesondheidsorgdeskundige indien jy enige ander medisyne neem (dit sluit komplementêre of tradisionele medisynes in.) Sien Moenie **VEXINE** neem nie.

Sê vir jou dokter indien jy enige van die volgende medisynes neem of gebruik:
- Monoamienoksidase-inhibeerders (MAOI's) (gebruik om depressie of Parkinson se siekte te behandel)
- Selektiewe serotonienheropname-inhibeerders (SSRI's) of litium
- Sentralesenuweestelselstimulante (kinidien, amiodaroon, sotalol, dofetilied)
- sommige antipsigotika (bv. tioridasien)
- sommige makroliede (bv. eritromisien)
- sommige antihistamiene
- sommige kinoloon-antibiotika (bv. moksifloksasien)
- Sekere medisynes kan die manier wat **VEXINE** deur jou liggaam beweeg, affekteer (atasanavir, klaritromisien, indinavir, itrakonasool, vorikonasool, posakonasool, ketokonasool, nelfinavir, ritonavir, sakinavir en telitromisien)
- **VEXINE** kan die manier wat sekere medisynes deur die liggaam beweeg, affekteer (litium, diasepaam, imipramien, haloperidol, risperidoon, metoprolol en indinavir).
- Medisynes vir gewigsverlies (dit word aanbeveel dat medisynes vir gewigsverlies nie saam met **VEXINE** geneem word nie).

VEXINE met kos, drinkgoed en alkohol:
Vermy die inname van alkohol terwyl jy **VEXINE** neem.

Swangerskap, borsvoeding en vrugbaarheid
Moenie **VEXINE** neem indien jy swanger is nie.

VEXINE word by die mens in moedersmelk uitgeskei. Pasiënte moet aangeraai word om nie te borsvoed indien hulle **VEXINE** neem nie.

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of gesondheidsorgdeskundige voordat jy **VEXINE** neem.

Bestuur en gebruik van masjiene
VEXINE kan jou oordeelsvermoë, denkwyse en motoriese vaardighede belemmer. Wees dus versigtig wanneer gevaarlike masjiene, insluitende motorvoertuie, hanteer word, totdat jy seker is dat venlafaksien jou nie nadelig affekteer nie.

Belangrike inligting oor party van die bestanddele van VEXINE
VEXINE bevat laktosemonohidraat, 'n suiker. Indien jy onverdraagsaam vir laktosemonohidraat is, raadpleeg dus asseblief eers jou dokter voordat jy **VEXINE** neem.

3. Hoe om VEXINE te neem
Moenie medisynes wat vir jou voorgeskryf is, met enigiemand anders deel nie. Neem **VEXINE** altyd presies soos wat jou dokter vir jou aangedui het. Vra gerus jou dokter of apteker indien jy onseker is.

Jou dokter sal jou inlig hoe lank jou behandeling met **VEXINE** gaan duur.

VEXINE moet heel ingesluk word, met vloeistof. Moenie die kapsule verdeel, fyndruk, kou of in water plaas nie.

VEXINE moet een keer daagliks op min of meer dieselfde tyd toegedien word, óf soggens óf saans.

Neem **VEXINE** met kos. Die gebruiklike aanbevole dosis **VEXINE** is 75 mg, een keer daagliks gegee. Indien nodig kan jou dokter die dosis verhoog tot 150 mg, een keer daagliks gegee. Indien nodig kan die dosis verder verhoog word tot soveel as 225 mg, een keer daagliks gegee.

Dosisverhogings moet geleidelik gedoen word en jou dokter gaan vir jou verduidelik hoe om dit te doen.

Die verlengdevrystelling-formule bevat sferoïede (effens afgeplatte balletjies), wat die medisyne stadig in die spysverteringskanaal vrystel. Die onoplosbare deel van hierdie sferoïede word uitgeskei en kan in die ontlasting gesien word.

Indien jy meer VEXINE neem as wat jy behoort te neem
In geval van oordosering, raadpleeg sonder versuim jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Oordosering met **VEXINE** is hoofsaaklik aangemeld met gelyktydige gebruik van alkohol en/of ander medisyne (sien ander medisyne en **VEXINE**).
Die simptome van 'n moontlike oordosering kan 'n vinnige of stadige hartklop insluit, veranderings in die elektriese aktiwiteit van jou hart wat in toetse gesien kan word, lae bloeddruk, lae bloedsuiker, duiseligheid, veranderings in bewustheidsvlak (wat wissel van slaperigheid tot koma), dowwe visie, stuiptrekkings of toevalle, braking en dood.

Indien jy 'n dosis VEXINE oorgeslaan het
Indien jy 'n dosis vergeet het, neem dit sodra jy onthou behalwe as dit byna tyd is vir die volgende dosis. Moenie 'n dubbele dosis neem om te vergoed vir die individuele dosisse wat oorgeslaan is nie.

4. Moontlike newe-effekte
VEXINE kan newe-effekte hê.

Nie alle newe-effekte wat vir **VEXINE** gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou verswak of indien jy enige ongunstige effekte ondervind terwyl jy **VEXINE** neem, moet jy asseblief jou dokter, apteker of gesondheidsorgdeskundige raadpleeg.

Indien enige van die volgende voorkom, hou op om **VEXINE** te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Geswelde gesig of tong, of kortasemheid of moeisame asemhaling, dikwels met veluitslag (dit kan 'n ernstige allergiese reaksie wees)
- Toevalle, stuiptrekkings of konvulsies
- Vinnige of onegalige hartklop, blosing of floute

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ondervind, mag jy 'n ernstige reaksie op **VEXINE** gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Indien jy enige van die volgende opmerk, sê onmiddellik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Erge gevoeligheid, styfheid of swakheid van die spiere, veral indien dit met donker urine gepaard gaan (dit mag veroorsaak word deur afbraak van spiere, wat tot nierprobleme lei – "rabdomiolise")
- Erge buik- of rugpyn (wat 'n ernstige probleem in die dermkanaal, lewer of pankreas kan aandui)
- Hoë liggaamstemperatuur met stywe spiere, verwardheid en agitasie, en sweting of indien jy rukkerige spierbewegings ervaar wat jy nie kan beheer nie. Dit mag simptome van 'n ernstige toestand bekend as neuroleptiese maligne sindroom wees
- Euforie, lomerigheid, volgehoue vinnige oogbewegings, lompheid, rusteloosheid, gevoel van dronkheid, sweting of rigiede spiere, wat simptome van serotonergiese sindroom is
- Gereelde of ongewone kneusing of bloeding, soos neusbloedings (dit kan aandui dat **VEXINE** 'n effek op jou bloed gehad het, en dit mag nodig wees om daarvoor te toets)
- Voel "hoog" of uitermatig opgewonde (manie of hipomanie).

Al hierdie newe-effekte is ernstig. Jy mag dringend mediese sorg benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- Verminderde eetlus
- Hoofpyn, ongewone moegheid of swakheid, sweting, duiseligheid, droë mond, sukkel om te slaap of lomerigheid, senuweeagtigheid
- Verandering in seksuele funksie, bv. abnormale ejakulasie by mans, kan nie orgasme bereik nie
- Verandering in eetlus of ontlastingspatroon, diarree of hardlywigheid, buikongemak, braking, slegte spysvertering, gewigsverlies of -toename
- Volgehoue probleme om aan die slaap te raak (insomnia)
- Agitasie, verwardheid, abnormale drome
- Gevoel van rusteloosheid of jy voel dat jy nie kan stilsit of stilstaan nie
- Gewysigde smaaksensasie
- Visuele belemmering, kan nie die oë fokus nie, veral op naby voorwerpe, dowwe visie, verwyding van die pupille
- Tinnitus (gesuis in die ore)
- Versnelde hartklop of 'n dawerende hartklop
- Hoë bloeddruk en warm gloed
- Sukkel om asem te haal (dispnee), gaap
- Oormatige sweetafskeiding, insluitende nagsweet
- Veluitslag en jeukerigheid
- Verhoogde spiertonus met verminderde kapasiteit van die spier om te strek
- Voel meer as gewoonlik die behoefte om toilet toe te gaan of sukkel om te urineer
- Versteurings van menstruasie by vrouens
- Uitputting, abnormale fisieke swakheid, kouekoors
- Verhoogde bloedcholesterol (jou dokter gaan 'n bloedtoets laat uitvoer om dit te bepaal)

Newe-effekte wat minder dikwels voorkom:
- Ontoepaslike afskeiding van die hormoon vasopressien (beheer bloeddruk)
- Verhoogde vlakke van prolaktien in die bloed, wat abnormale produksie van borsmelk veroorsaak
- 'n Toestand wat voorkom wanneer die natriumvlak in die bloed te laag is (bekend as hiponatremie, waar die liggaam te veel water terughou)
- Voel "hoog" of oormatig opgewonde (toestand bekend as manie, hipomanie)
- Disoriëntasie en verwardheid, dikwels met gepaardgaande hallusinasies (toestand bekend as delirium)
- Abnormale orgasme
- Gebrek aan belangstelling, entoesiasme of besorgdheid
- Klem of kners tande, spierspasma
- Selfdoodideasie en selfdoodgedrag
- Voel aggressief of het aggressiewe gedagtes
- Floute of 'n skielike, tydelike verlies aan bewussyn (toestand bekend as sinkopee)
- 'n Skielike, onwillekeurige trekking, bewing of spasma van 'n spier (toestand bekend as mioklonus)
- Balansversteuring, abnormaliteit of belemmering van willekeurige beweging (toestand bekend as diskinese)
- Onwillekeurige spiersametrekkings wat herhaalde of draaiende bewegings veroorsaak (toestand bekend as distonie)
- Verhoging van druk in oog (toestand bekend as hoeksluiting-gloukoom)
- Stywe, rukkerige bewegings van jou gesig en liggaam wat jy nie kan beheer nie (toestand bekend as trae diskinese)
- Gevoel dat jy in die rondte draai, draaiduiseling (toestand bekend as vertigo)
- Abnormale hartritme, vinnige hartklop, onegalige harttempo
- Voel duiselig of onvas wanneer jy staan weens 'n val in bloeddruk (veral by bejaarde pasiënte)
- Alle vorms van bloeding in die spysverteringskanaal, vanaf die mond tot by die rektum (toestande bekend as gastro-intestinale bloeding)
- Geel verkleuring van die vel en oë
- Galbulte, haarverlies, verkleuring van die vel weens onderhuidse bloeding, tipies deur kneusing veroorsaak
- Pynlose swelling onder die vel
- Jou vel is meer sensitief vir sonlig
- 'n Seldsame, ernstige versteuring van jou vel en slymvliese. Dit is gewoonlik 'n reaksie op 'n medisyne of 'n infeksie. Dit begin dikwels met griepagtige simptome, gevolg deur 'n pynlike rooi of pers uitslag, wat versprei en blase vorm (toestand bekend as Stevens-Johnsonsindroom)
- 'n Potensieel lewensbedreigende dermatologiese versteuring gekenmerk deur wydverspreide eriteem en nekrose (toestand bekend as toksiese epidermale nekrolise)
- 'n Velversteuring gekenmerk deur teikenvormige letsels (toestand bekend as erythema multiforme)
- Verlies van blaasbeheer
- Verlengde bloedingstyd
- Abnormaliteite van die bloed wat jou dokter met behulp van 'n bloedtoets gaan bepaal.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker daaroor in.

Rapportering van newe-effekte
Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety-toepassing (Medsafety X SAHPRA) en e-rapporteringplatform (who-umc.org), wat op SAHPRA se webwerf beskikbaar is. Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die veiligheid van **VEXINE** te verskaf.

5. Hoe om VEXINE te bewaar
BEWAAR ALLE MEDISYNES BUITE BEREIK VAN KINDERS.
Bêre by of onder 25 °C.
Hou in die oorspronklike verpakking tot nodig vir gebruik.
Moenie in die badkamer bêre nie.
Moenie gebruik ná die vervaldatum wat op die etiket voorkom nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) wegdoen nie.

6. Inhoud van die verpakking en ander inligting
Wat VEXINE bevat
Die aktiewe bestanddeel is venlafaksien.

VEXINE 37,5 mg:
Elke verlengdevrystelling-kapsule bevat venlafaksienhidrochloried gelykstaande aan 37,5 mg venlafaksien.
Bevat suiker: 43,571 mg sukrose.

VEXINE 75 mg:
Elke verlengdevrystelling-kapsule bevat venlafaksienhidrochloried gelykstaande aan 75 mg venlafaksien.
Bevat suiker: 87,142 mg sukrose.

VEXINE 150 mg:
Elke verlengdevrystelling-kapsule bevat venlafaksienhidrochloried gelykstaande aan 150 mg venlafaksien.
Bevat suiker: 174,285 mg sukrose.

Die ander bestanddele is etielsellulose, hipromellose, metanol, metileenchloried, suikerballetjies.

Samestelling van die kapsuledoppie:
Gelatien, swart ysteroksied (K.I. nr. 77499), rooi ysteroksied (K.I. nr. 77491), natriumlourielsulfaat, titaandioksied (K.I. nr. 77891).

Samestelling van die ink:
Swart ysteroksied (K.I. nr. 77499), butielalkohol, gedehidreerde alkohol, isopropielalkohol, kaliumhidroksied, propileenglikol, gesuiwerde water, skilferlak, sterk ammoniakoplossing.

Hoe VEXINE lyk en inhoud van die verpakking
VEXINE 37,5 mg
Wit tot naaswit sferiese tot ovaalvormige korrels gevul in 'n leë harde gelatienkapsule (grootte "3") met 'n ondeursigtige grys doppie en ondeursigtige perskekleurige romp, met "E" op die doppie en "73" op die romp gedruk met eetbare swart ink.

VEXINE 75 mg
Wit tot naaswit sferiese tot ovaalvormige korrels gevul in 'n leë harde gelatienkapsule (grootte "1") met 'n ondeursigtige perskekleurige doppie en ondeursigtige perskekleurige romp, met "E" op die doppie en "74" op die romp gedruk met eetbare swart ink.

VEXINE 150 mg
Wit tot naaswit sferiese tot ovaalvormige korrels gevul in n leë harde gelatienkapsule (grootte "0") met n ondeursigtige donkeroranje doppie en ondeursigtige donkeroranje romp met "E" op die doppie en "89" op die romp met eetbare swart ink gedruk.

Stulpverpakking:
30 kapsules word in n stulpstrook van mikron PVC / 25 mikron PE / 90 gm^{-2} PVdc film - aluminiumfoelie verpak. Elke karton bevat 3 stulpstroke met 10 kapsules elk. Die stulpstroke word in voorafgedrukte kartonne met n inligtingsblad verpak.

Verpakkingsgrootte: 30's - Elke kartonhouer bevat 3 stulpstroke wat 10 kapsules elk bevat.

Houder van die Registrasiesertifikaat
Aurogen South Africa (Edms.) Bpk
Woodhill Office Park, Gebou 1, Eerste Vloer
Phillip Engelbrechtlaan 53
Meyersdal, Uitbr. 12
1448 Johannesburg
Suid Afrika
Tel.nr.: +27 11 867 9100

Hierdie inligtingsblad is laas hersien:
20 Maart 2026

REGISTRASIENOMMERS:
VEXINE 37,5 mg: 47/1.2/0080
VEXINE 75 mg: 47/1.2/0081
VEXINE 150 mg: 47/1.2/0082

AUROBINDO Packaging Development	Product Name: VEXINE	Component: Leaflet	Item Code: P1540309	Date & Time: 20.04.2026 & 10:02 AM No. of Colours: 1
	Customer / Country: Aurogen_South Africa Unit-3	Version No.: 07	Reason of Issue: New	Black
Team Leader: Kiran Kumar	Dimensions: A/s: 360 x 660 mm F/size: 40 x 60 mm	Font Type: Helvetica	Font Size: 7 pt	
Initiator: Bhogeswara Rao				
Design Agency: vakils APL_LN: 3650	Pharmacode: 40309			

Date - Designer - Run:			Reviewed / Approved by
1. 12-AUG-2025 (Dipali) - FR	8. 15-APR-2026 (Mayuri) - RR4	15.	
2. 12-AUG-2025 (Dipali) - FR	9. 20-APR-2026 (Mayuri) - RR5	16.	
3. 20-FEB-2026 (Satish) - RR1	10.	17.	
4. 31-MAR-2026 (Satish) - FR1	11.	18.	
5. 10-APR-2026 (Satish) - FR2	12.	19.	
6. 13-APR-2026 (Satish) - RR2	13.	20.	
7. 14-APR-2026 (Satish) - RR3	14.		

Additional Information: Supercede Item Code: P1539767

Sign / Date