# Front Side

335 mm

370 mm

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS** S5

**VEXALIN XR 75 mg** (Extended release capsules)
Venlafaxine hydrochloride 75 mg
Sugar free

**VEXALIN XR 150 mg** (Extended release capsules)
Venlafaxine hydrochloride 150 mg
Sugar free

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


## 1. What VEXALIN XR is and what it is used for

**VEXALIN XR** contains the active substance venlafaxine.
**VEXALIN XR** is an antidepressant that belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). **VEXALIN XR** is used in adults to treat:
- depression, including depression with associated anxiety
- and the following anxiety disorders: generalised anxiety disorder and social anxiety disorder (fear or avoidance of social situations).

## 2. What you need to know before you take VEXALIN XR

**Do not take VEXALIN XR:**
- If you are allergic (hypersensitive) to venlafaxine or any of the other ingredients of **VEXALIN XR** listed in Section 6.
- If you are also taking or have taken any time within the last 14 days any medicines known as irreversible monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease. Taking an irreversible MAOI together with **VEXALIN XR**, can cause side effects such as nausea, vomiting, dizziness, tremor, flushing, muscle twitching, elevated body temperature, profuse sweating, seizures or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking **VEXALIN XR** before you take any MAOI.
- If you are pregnant or breastfeeding.
- If you are under 18 years of age.

**Warnings and precautions**
Take special care with **VEXALIN XR**:
- if you are taking other medicines to treat depression.
- if you have had seizures (fits).
- If you previously have had mental illness (mania) or if you or a family member has a history of bipolar disorder as **VEXALIN XR** may cause mood swings (mood of excitement, over-activity and uninhibited behaviour).
- if you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- if you have high blood sugar (diabetes).
- if you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when you first start taking antidepressants or when you doctor makes changes to the dose. If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.
  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 might 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.
- if you have any pre-existing heart condition or disease which might affect your blood pressure. **VEXALIN XR** may cause your blood pressure to increase and in some cases requiring immediate treatment to lower your blood pressure. Your doctor will test your blood pressure before start of treatment, after a dose increase and regularly thereafter.
- if you suffer from bleeding tendencies or if you are taking medicines known as anti-coagulants (e.g. warfarin) or platelet inhibitors (e.g. aspirin) as the risk of skin and mucous membrane bleeding, including bleeding from the stomach wall, may be increased in patients taking **VEXALIN XR**.
- if you are taking any medicines for weight loss (e.g. phentermine). **VEXALIN XR** is not indicated for weight loss, alone or in combination with other products.
- There has been a relation between a group of medicines called SSRI and SNRI and heavy bleeding following birth. **VEXALIN XR** belongs to the group of medicines called SSRIs. If you have any bleeding disorders or are pregnant, your doctor will have to change your treatment to an alternative group of medicines

While taking **VEXALIN XR**:
- Contact your doctor immediately if you experience an allergic reaction to **VEXALIN XR** with symptoms of swelling of the face, lips, tongue, and throat, difficulty breathing as well as a diffuse skin rash.
- Tell your doctor if you notice the following changes in behaviour while taking **VEXALIN XR**: anxiety, agitation, panic attacks, insomnia, irritability, become hostile and aggressive, impulsive, feeling restless and unable to stand or sit still or suffering from mental illness. Your doctor may consider discontinuing therapy with **VEXALIN XR** if you did not have these symptoms prior to therapy with **VEXALIN XR**. Your dose will be gradually reduced if your doctor decides to discontinue your therapy with **VEXALIN XR**.
- Serotonin syndrome, a potentially life-threatening condition may occur with **VEXALIN XR** treatment, particularly when taken with other medicines. Examples of these medicines include:
  - Triptans (used for migraine)
  - Other medicines to treat depression, for instance SNRIs, SSRIs, tricyclics, or medicines containing lithium
  - Medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy and obesity)
  - Medicines containing linezolid, an antibiotic (used to treat infections)
  - Medicines containing moclobemide, a MAOI (used to treat depression)
  - Medicines containing sibutramine (used for weight loss)
  - Medicines containing tramadol, fentanyl, tapentadol, pethidine, or pentazocine (used to treat severe pain)
  - Medicines containing dextromethorphan (used to treat coughing)
  - Medicines containing methadone (used to treat opioid drug addiction or severe pain)
  - Medicines containing methylene blue (used to treat high levels of methaemoglobin in the blood)
  - Products containing St. John's Wort (also called Hypericum perforatum, a natural or herbal remedy used to treat mild depression)
  - Products containing tryptophan (used for problems such as sleep and depression)
  - Antipsychotics (used to treat a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, unclear reasoning and becoming withdrawn)

Inform your doctor or go to the nearest hospital if you notice a combination of the following: restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea and vomiting.
- **VEXALIN XR** may cause eye problems such as dilated pupils, raised pressure and glaucoma. Inform your doctor if you notice any changes to your eyes.
- Tell your doctor if you have been told you have an abnormal heart rhythm as **VEXALIN XR** may cause an increase in heart rate, especially at high doses.
- If you experience palpitations or irregular heart beat or fainting spells during the period of treatment, you should inform your doctor immediately.
- Inform your doctor if you experience aggressive behaviour during treatment with **VEXALIN XR** especially upon start, dose reduction or discontinuation of treatment.
- **VEXALIN XR** may cause low levels of sodium in the blood and/or the syndrome of inappropriate antidiuretic hormone secretion (SIADH); a condition that causes your body to make too much antidiuretic hormone (ADH). ADH is a chemical that helps keep the right balance of fluids in your body. Increased ADH may cause too much water to remain inside your body and chemicals in your blood, such as salt, may decrease. This may prevent your organs from working properly. This side effect may occur especially if you are elderly, are taking diuretics (water pills) or are dehydrated.
- Your doctor will monitor your cholesterol levels periodically as **VEXALIN XR** may increase the cholesterol levels in your blood.
- If your doctor thinks that you no longer need **VEXALIN XR**, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop using **VEXALIN XR**, especially when **VEXALIN XR** is stopped suddenly or the dose is reduced too quickly (see POSSIBLE SIDE EFFECTS).
- **VEXALIN XR** may cause symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment.
- **VEXALIN XR** may cause a sensation of restlessness or an inability to sit or stand still during the first few weeks of treatment. You should tell your doctor if this happens to you.
- **VEXALIN XR** may cause dry mouth. Take special care in your dental hygiene as a dry mouth may increase the risk of dental caries.
- Your blood glucose levels may be altered due to **VEXALIN XR**. Therefore, the dosage of your diabetes medicines may need to be adjusted.
- You are unlikely to develop tolerance or become addicted to **VEXALIN XR** when taken over a long period of time, however, your doctor will monitor your treatment for signs of tolerance or addiction.
- **VEXALIN XR** can be used safely in healthy elderly patients.

**Children and adolescents**
- **VEXALIN XR** should not be given to children under 18 years of age as it has not been proven to be safe and effective in this age group.

**Other medicines and VEXALIN XR**
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
Only take other medicines while you are on **VEXALIN XR** if your doctor tells you that you can.
You should tell your doctor if you are taking the following medicines:
- Monoamine oxidase inhibitors (MAOIs) such as moclobemide (an antidepressant) and linezolid (an antibiotic).
- Medicines to treat depression, for instance, medicines known as SNRIs or SSRIs and medicines containing lithium.
- Medicines that increase the level of serotonin: Triptans, tramadol, tryptophan, SSRIs (such as paroxetine and fluoxetine), SNRIs (such as venlafaxine), tricyclic antidepressants (such as clomipramine, amitriptyline), pethidine, St John's Wort (herbal medicine for depression) and MAOIs (such as moclobemide and linezolid). These medicines increase the risk of side effects; if you experience any unusual symptoms while taking any of these medicines together with **VEXALIN XR**, you should see your doctor.
- Supplements containing tryptophan (used for problems such as sleep and depression).
- Indinavir (for HIV treatment)
- Desipramine (for depression)
- Sibutramine (used for weight loss).
- Ketoconazole (an antifungal medicine).
- Haloperidol or risperidone (to treat psychiatric conditions).
- Metoprolol (a beta blocker to treat high blood pressure and heart problems)
- Medicines that can affect your heart rhythm. Examples of these medicines include:
  - Antidysrhythmics such as quinidine, amiodarone, sotalol or dofetilide (used to treat abnormal heart rhythm)
  - Antipsychotics such as thioridazine (See also Serotonin syndrome above)
  - Antibiotics such as erythromycin or moxifloxacin (used to treat bacterial infections)
  - Antihistamines (used to treat allergy).

Inform your doctor that you are taking **VEXALIN XR** if blood tests are required to test for phencyclidine (PCP) or amphetamine.

**VEXALIN XR with food and drink and alcohol**
Alcohol should be avoided while being treated with **VEXALIN XR**.

**Pregnancy, breastfeeding and fertility**
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **VEXALIN XR**.
- Tell your doctor if you become pregnant, or you are trying to become pregnant, while you are taking **VEXALIN XR**. You should not take **VEXALIN XR** if you are pregnant.
- If you take **VEXALIN XR** near the end of your pregnancy, your baby might have some symptoms when it is born. These usually begin at birth or within a few days of your baby being born. These symptoms may include not feeding properly, trouble with breathing and prolonged hospitalisation.
- Tell your doctor if you are breastfeeding. You should not take **VEXALIN XR** while breastfeeding.

**Driving and using machines**
**VEXALIN XR** may cause impairment of judgement, thinking or muscle control. It is not always possible to predict to what extent **VEXALIN XR** may interfere with your daily activities. You should not engage in the above activities until you are aware of the extent to which **VEXALIN XR** affects you.

## 3. How to take VEXALIN XR

- Do not share medicines prescribed for you with any other person.
- Always take **VEXALIN 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 **VEXALIN XR** will last. Do not stop treatment early.
- If you have the impression that the effect of **VEXALIN XR** is too strong or too weak, tell your doctor or pharmacist.
- Stay under a healthcare provider's care when taking **VEXALIN XR**. Do not change your treatment or stop treatment without first talking with your healthcare provider.

**Recommended dose of VEXALIN XR:**
- **VEXALIN XR** capsules are for oral use.
- Your doctor will tell you how many **VEXALIN XR** to take and how long you should continue to take them.
- The usual recommended starting dose for treatment of depression, generalised anxiety disorder and social anxiety disorder is 75 mg per day. The dose can be raised by your doctor gradually, and if needed, even up to a maximum dose of 375 mg daily for depression. The maximum dose for generalised anxiety disorder and social anxiety disorder is 225 mg/day.
- Take **VEXALIN XR** at approximately the same time each day, either in the morning or in the evening. Capsules must be swallowed whole with fluid and not opened, crushed, chewed or dissolved. **VEXALIN XR** should be taken with food.
- If you have liver or kidney problems, your doctor will adjust your dose of **VEXALIN XR**.
- Do not be concerned if you see small white granules or particles in your stools after taking **VEXALIN XR**. **VEXALIN XR** 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 VEXALIN 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.
The symptoms of a possible overdose may include a rapid heartbeat, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures or fits, and vomiting.

**If you forget to take VEXALIN XR**
If you forget to take a dose, take it as soon as you remember, and then continue as before.
Do not take a double dose to make up for forgotten individual doses.

**If you stop taking VEXALIN XR**
Do not stop taking your capsules just because you feel better. It is important that you carry on taking **VEXALIN XR** for as long as your doctor tells you.
If your doctor thinks that you no longer need **VEXALIN XR**, he/she may ask you to reduce your dose slowly before stopping treatment altogether. After stopping long and short-term **VEXALIN XR** treatment, you need to know that you may experience certain side effects. Some patients may experience symptoms such as mood swings, anxiety, agitation, nervousness, confusion, insomnia or other sleep disturbances, fatigue, sleepiness, tingling, dizziness, seizures, spinning sensation (vertigo), headache, flu-like symptoms, ringing in the ears (tinnitus), impaired coordination and balance, tremor, sweating, dry mouth, loss of appetite, diarrhoea, nausea and vomiting.
Your doctor will advise you on how you should gradually discontinue **VEXALIN XR** treatment. If you experience any of these or other symptoms that are troublesome, ask your doctor for further advice.

## 4. Possible side effects

**VEXALIN XR** can have side effects.
Not all side effects reported for **VEXALIN XR** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **VEXALIN XR**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **VEXALIN XR** and tell your doctor immediately or go to the casualty department at your nearest hospital:
Get emergency medical help if you have any of these **signs of an allergic reaction:**
- Hives; shortness of breath or difficulty breathing; swelling of your face, lips, tongue, or throat.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **VEXALIN XR**. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Feeling dehydrated, having low levels of sodium in the blood (mostly in elderly people; the symptoms may include feeling dizzy, weak, confused, sleepy or very tired, or feeling or being sick, more serious symptoms are fainting, fits or falls), retention of water by the body (syndrome of inappropriate secretion of anti-diuretic hormone (SIADH)).
- Having convulsions (fits).
- Thoughts of suicide and self-harm.
- Serotonin syndrome, a potentially life-threatening condition may occur with **VEXALIN XR** treatment. Inform your doctor or go to the nearest hospital if you notice a combination of the following: restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, changes in blood pressure, overactive reflexes, diarrhoea, nausea, vomiting and coma.
- In its most severe form, serotonin syndrome can resemble Neuroleptic Malignant Syndrome (NMS). Signs and symptoms of NMS may include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).
- Symptoms of rhabdomyolysis (breakdown of muscle tissue): dark, red, or cola-coloured urine, decreased urine output, general weakness, muscle stiffness or aching, muscle tenderness, weakness of the affected muscles.
- Fast and/or irregular heartbeat or abnormal fast heart rate, changes on the ECG referred to as a prolongation of the QT-interval, i.e., delayed conduction of electrical signals.
- Coughing, wheezing, shortness of breath and a high temperature, which are symptoms of inflammation of the lungs associated with an increase in white blood cells (pulmonary eosinophilia).
- Vomiting blood, or black tarry stools (faeces).
- Inflammation of the pancreas with symptoms including upper abdominal pain, nausea and vomiting.
- Inflammation of the liver or liver failure that may cause abdominal pain and yellowing of the skin or whites of the eyes (jaundice).
- Stevens-Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals).
- Severe skin rash, itching or hives (elevated patches of red or pale skin that often itch)
- Prolonged bleeding - if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop.
- Contraction of the jaw muscle (lockjaw).

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:
- unusual dreams, less sex drive, trouble sleeping, nervousness
- dizziness, dry mouth, feeling sluggish, numbness, including numbness, pricking or tingling of the skin, feeling sleepy, tremor, altered or impaired sense of taste
- eye problems such as blurred eyesight, dilated pupils, inability of the eye to automatically change focus from distant to near objects
- tinnitus (hearing sound in the ear when there is no external sound)
- increased blood pressure, flushing
- increased yawning, difficulty breathing
- decreased appetite, feeling sick (nausea), constipation, being sick (vomiting)
- difficulties passing urine
- problems getting an erection, changes in ejaculation/orgasm in males
- weakness, fatigue, pain, stomach pain, back pain, chest pain.

*Less frequent side effects:*
- bruising of the skin
- feeling indifferent, hallucinations, psychiatric problems, such as hyperactivity and feeling unusually overexcited
- sudden involuntary jerks or twitches of the muscles
- difficulty sleeping, feeling disorientated, lack of motivation
- fainting, light headedness or fainting on standing up
- inflammation of the large intestine (leading to diarrhoea), burping, difficulty swallowing, inflammation of the mouth, bad breath
- skin rash, sensitivity to sunlight
- difficulty or inability to pass urine
- abnormal orgasm in females
- feeling cold or hot, thirst, shivering, feeling unwell, abnormal gait
- weight gain
- changes in blood test results (decrease in blood sodium, decrease in white blood cell count, blood sugar increased, platelet count decreased, weight increased, weight decreased, liver enzymes increased.

*Frequency unknown:*
- bleeding gums
- reduced number of platelets in your blood, leading to an increased risk of bruising or bleeding
- signs of infection, such as high temperature, chills, shivering, headaches, sweating, flu-like symptoms. This may be the result of a blood disorder (reduction in certain white blood cells) which leads to an increased risk of infection.
- increased prolactin levels in the blood (abnormal breast milk production)
- confusion; feeling separated (or detached) from yourself, agitation, disorientation and confusion often accompanied by hallucination (delirium), aggression, loss of memory, anxiety, depression, lack of feeling or emotion; abnormal thinking, inappropriate behaviour
- headache, difficulty controlling movement e.g. lack of coordination or involuntary movements of the muscles, muscle stiffness, sensation of restlessness or an inability to sit or stand still, repetitive, involuntary movements such as grimacing and eye blinking, numbness or a decreased sense of touch, poor sleep quality
- increased pressure in the eyes (glaucoma)
- vertigo (spinning sensation)
- feeling the heart pumping in the chest
- low blood pressure
- sore throat, runny or stuffed nose
- grinding or clenching the teeth, increased appetite, diarrhoea, heartburn or indigestion, burping or belching, breaking wind
- muscle pain, muscle spasm
- sweating (including night sweats), hives, itchy skin rash, abnormal hair loss
- needing to pass more urine than normal
- menstrual disorders associated with increased bleeding or increased irregular bleeding, haemorrhage (heavy bleeding) after giving birth.

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **VEXALIN XR**.

## 5. How to store VEXALIN XR

Store at or below 25 °C.
Protect from light and moisture.
Keep the blisters in the carton until required for use.
Keep HDPE containers tightly closed.
KEEP OUT OF REACH OF CHILDREN
Do not store in a bathroom.
Do not use after the expiry date stated on the label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of pack and other information

**What VEXALIN XR contains**
- The active substance is venlafaxine hydrochloride 75 mg/150 mg.
- The other ingredients are low substituted hydroxy propyl cellulose, corn starch, microcrystalline cellulose, ethyl cellulose, hydroxypropyl methyl cellulose, purified talc, hard gelatin capsules containing titanium dioxide, iron oxide red, gelatin and sodium lauryl sulfate. In addition **VEXALIN XR 75 mg** contain iron oxide yellow.

**What VEXALIN XR looks like and contents of the pack**
**VEXALIN XR 75 mg** (Extended Release Capsules)
Peach Cap/peach body, size '1' capsules containing white to off white extended release beads with 'L 87' on cap and '75' on body imprinted with red ink.
**VEXALIN XR 150 mg** (Extended Release Capsules)
Dark orange cap/dark orange body, size '0el' capsules containing white to off white extended release beads with 'L 88' on cap and '150' on body imprinted with white ink.

**Blister pack:**
Plain, silver coloured, 25 µ aluminium foil/ 6-8 gsm HSL as the lidding material and clear, transparent PVC/PE/PVdC, 250 µ/25 µ/90 gsm, as the forming material, packed in a pre-printed unit carton with 10, 28 or 30 capsules.
**HDPE container pack:**
Capsules are packed in white, opaque, round 40 ml or 60 ml HDPE container for **VEXALIN XR** 75 mg and 60 ml HDPE container for **VEXALIN XR** 150 mg with 33 mm neck finish closed with 33 mm white polypropylene closure with wad having induction sealing liner. Each container contains 28 or 30 capsules with a silica gel. The containers are placed in a pre-printed outer carton with a package insert.

**Holder of Certificate of Registration and Manufacturer**
**MACLEODS PHARMACEUTICALS SA (PTY) LTD**
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1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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20 April 2021

**Registration number**
**VEXALIN XR 75 mg** (Extended release capsules): 51/1.2/0059.057
**VEXALIN XR 150 mg** (Extended release capsules): 51/1.2/0060.058

**Access to the corresponding Professional Information**
The corresponding professional information can be accessed at https://www.macleodspharma.com/or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

**VEXALIN XR 75/150**
**(Extended release capsules)**
PM03930102

# Back Side

335 mm

380 mm

**PASIËNTINLIGTINGSBLAD**

**SKEDULERINGSTATUS:** S5

**VEXALIN XR 75 mg** (Verlengde-vrystellings kapsules)
Venlafaksienhidrochloried 75 mg
Suikervry

**VEXALIN XR 150 mg** (Verlengde-vrystellings kapsules)
Venlafaksienhidrochloried 150 mg
Suikervry

**Lees hierdie hele inligtingsblad aandagtig deur, voordat jy VEXALIN XR begin gebruik**
- Hou hierdie inligtingsblad. Dit mag wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **VEXALIN XR** is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander mense te deel nie. Selfs al het hulle dieselfde simptome as jy, kan dit vir hulle skadelik wees.

**Wat in hierdie inligtingsblad is**

1. Wat **VEXALIN XR** is en waarvoor dit gebruik word.
2. Wat jy behoort te weet voordat jy **VEXALIN XR** gebruik.
3. Hoe om **VEXALIN XR** te gebruik
4. Moontlike newe-effekte
5. Hoe om **VEXALIN XR** te berg
6. Inhoud van die pak en ander inligting


## 1. Wat VEXALIN XR is en waarvoor dit gebruik word

**VEXALIN XR** bevat die aktiewe bestanddeel venlafaksien.
**VEXALIN XR** is 'n antidepressant wat behoort tot 'n groep medisyne genaamd serotonien- en norepinefrienheropname inhibeerders (SNHI's). **VEXALIN XR** word in volwassenes gebruik vir die behandeling van:
- depressie, insluitend depressie met geassosieerde angstigheid
- en die volgende angsversteurings: algemene angsversteuring en sosiale angsversteuring (vrees of vermyding van sosiale situasies).

## 2. Wat jy behoort te weet voordat jy VEXALIN XR neem

**Moet nie VEXALIN XR neem:**
- Indien jy allergies (hipersensitief) vir venlafaksien of enige van die ander bestanddele van **VEXALIN XR** soos gelys in afdeling 6, is nie.
- Indien jy ook enige medisyne bekend as onomkeerbare monoamienoksidase-inhibeerders (MAOIs) gebruik, of gebruik het, binne die laaste 14 dae, om depressie of Parkinson se siekte te behandel. Indien jy 'n onomkeerbare MAOI saam met **VEXALIN XR** neem, kan dit newe-effekte veroorsaak, soos naarheid, braking, duiseligheid, bewing, blosing, spiertrekkings, verhoogde liggaamstemperatuur, oorvloedige sweet, aanvalle of selfs lewensbedreigende newe-effekte. Jy moet ook ten minste 7 dae wag nadat jy opgehou het met die gebruik van **VEXALIN XR** voordat jy enige MAOI neem.
- Indien jy swanger is of borsvoed nie.
- Indien jy jonger as 18 jaar oud is nie.

**Waarskuwings en voorsorgmaatreëls**
Neem spesiale sorg met **VEXALIN XR**:
- indien jy ander medisyne neem om depressie te behandel.
- Indien jy aanvalle (stuiptrekkings) gehad het.
- as jy voorheen geestesongesteldheid (manie) gehad het of as jy of 'n familielid 'n geskiedenis van bipolêre versteuring het, aangesien **VEXALIN XR** buierigheid kan veroorsaak (bui van opgewondenheid, ooraktiwiteit en ongeremde gedrag).
- as jy oogprobleme het, soos sekere soorte gloukoom (verhoogde druk in die oog).
- indien jy hoë bloedsuiker het (diabetes).
- as jy depressief is en/of angsversteurings het, kan jy soms daaraan dink om jouself leed aan te doen of om selfmoord te pleeg. Hierdie gedagtes kan toeneem wannneer jy vir die eerste keer antidepressante begin gebruik of wanneer jou dokter die dosering verander. Indien jy op enige tydstip daaraan dink om jouself leed aan te doen, of om selfmoord te pleeg, moet jy jou dokter kontak of onmiddellik na 'n hospitaal gaan. Jy mag dit moontlik nuttig vind om 'n familielid of hegte vriend te vertel dat jy depressief is en hulle te vra om hierdie inligtingsblad te lees. Jy kan hulle moontlik vra om jou te vertel indien hulle dink dat jou depressie of angstigheid vererger, of as hulle bekommerd is oor veranderinge in jou gedrag.
- indien jy 'n bestaande harttoestand of -siekte het wat jou bloeddruk kan beïnvloed. **VEXALIN XR** kan veroorsaak dat jou bloeddruk styg en in sommige gevalle onmiddellike behandeling vereis om jou bloeddruk te verlaag. Jou dokter sal jou bloeddruk toets voordat behandeling begin, na 'n dosisverhoging en gereeld daarna.
- as jy aan bloedingsneigings ly, of indien jy medisyne neem naamlik antistollingsmiddels (bv. warfarien) of plaatjie-inhibeerders (bv. aspirien), aangesien die risiko van bloeding van die vel en slymvlies, insluitend bloeding van die maagwand, kan verhoog wat in pasiënte wat **VEXALIN XR** neem.
- indien jy medisyne gebruik om gewig te verloor (bv. fentermien). **VEXALIN XR**, alleen of in kombinasie met ander produkte, word nie aangedui vir gewigsverlies nie.
- Daar was 'n verband tussen 'n groep medisyne genaamd SSHI en SNHI en swaar bloeding na geboorte. **VEXALIN XR** behoort tot die groep medisyne genaamd SSHI's. Indien jy bloedingsversteurings het of swanger is, sal jou dokter jou behandeling moet verander na 'n alternatiewe groep medisyne.

Terwyl **VEXALIN XR** geneem word:
- Kontak jou dokter onmiddellik indien jy 'n allergiese reaksie op **VEXALIN XR** ervaar met simptome soos swelling van die gesig, lippe, tong en keel, asemhalingsprobleme sowel as 'n verspreide veluitslag.
- Vertel jou dokter indien jy die volgende veranderinge in gedrag agterkom terwyl **VEXALIN XR** geneem word: angs, rusteloosheid, paniekaanvalle, slapeloosheid, geïrriteerdheid, vyandig en aggressief raak, impulsief, voel onrustig en kan nie stilstaan of -sit nie of ly aan geestesongesteldheid. Jou dokter kan dit oorweeg om behandeling met **VEXALIN XR** te staak, indien jy nie hierdie simptome gehad het voordat jy met **VEXALIN XR** behandeling begin het nie. Jou dosering sal geleidelik verminder word indien jou dokter besluit om jou behandeling met **VEXALIN XR** te staak.
- Serotoniensindroom, 'n potensieel lewensbedreigende toestand, kan voorkom met **VEXALIN XR** behandeling, veral as dit saam met ander medisyne geneem word. Voorbeelde van hierdie medisyne sluit in:
  - Triptane (gebruik vir migraine)
  - Ander medisyne om depressie te behandel, byvoorbeeld SNHI's, SSHI's, trisikliese middels, of medisyne wat litium bevat.
  - Medisyne wat amfetamiene bevat (gebruik om aandagtekort hiperaktiwiteit versteuring (ADHD), narkolepsie en vetsug te behandel.
  - Medisyne wat linesolied bevat, 'n antibiotikum (gebruik om infeksies te behandel)
  - Medisyne wat moklobemied bevat, 'n MAOI (gebruik om depressie te behandel)
  - Medisyne wat sibutramien bevat (gebruik vir gewigsverlies)
  - Medisyne wat tramadol, fentaniel, tapentadol, petidien, of pentasokien bevat (gebruik om erge pyn te behandel)
  - Medisyne wat dekstrometorfaan bevat (gebruik vir die behandeling van hoes)
  - Medisyne wat metadoon bevat (gebruik om opioïedmiddel afhanklikheid of erge pyn te behandel)
  - Medisyne wat metileenblou bevat (wat gebruik word om hoë vlakke van methemoglobien in die bloed te behandel)
  - Produkte wat Sint-Janskruid bevat (ook genoem *Hypericum perforatum*, 'n natuurlike- of kruiemiddel wat gebruik word vir die behandeling van ligte depressie)
  - Produkte wat triptofaan bevat (gebruik vir probleme soos slaap en depressie)
  - Antipsigotika (gebruik om 'n siekte te behandel met simptome soos om dinge wat nie daar is nie te hoor, te sien of waar te neem, verkeerde oortuigings, ongewone agterdog, onduidelike redenasie en teruggetrokke raak)

Stel jou dokter in kennis of gaan na die naaste hospitaal as jy 'n kombinasie van die volgende waarneem: rusteloosheid, hallusinasies, verlies aan koördinasie, vinnige hartklop, verhoogde liggaamstemperatuur, verandering in bloeddruk, ooraktiewe reflekse, diaree, koma, naarheid en braking.
- **VEXALIN XR** kan oogprobleme veroorsaak soos verwyde pupille, verhoogde druk en gloukoom. Stel jou dokter in kennis indien jy enige veranderinge in jou oë opmerk.
- Vertel jou dokter indien daar aan jou gesê is dat jy 'n abnormale hartritme het, aangesien **VEXALIN XR** 'n toename in hartklop kan veroorsaak, veral by hoë dosisse.
- As jy tydens die behandeling hartkloppings of onreëlmatige hartslag of floutes ervaar, moet jy dadelik jou dokter inlig.
- Stel jou dokter in kennis as jy aggressiewe gedrag ervaar tydens behandeling met **VEXALIN XR**, veral met die aanvang, dosisverlaging of staking van die behandeling.
- **VEXALIN XR** kan lae vlakke van natrium in die bloed en/of die sindroom van onvanpaste antidiuretiese hormoonafskeiding (SOADH) veroorsaak; 'n toestand wat veroorsaak dat jou liggaam te veel antidiuretiese hormoon (ADH) maak. ADH is 'n chemikalie wat help om die regte balans van vloeistowwe in jou liggaam te hou. Verhoogde ADH kan veroorsaak dat te veel water in jou liggaam oorbly en chemikalieë in jou bloed, soos sout, kan afneem. Dit kan verhoed dat jou organe reg werk. Hierdie newe-effek kan voorkom veral as jy bejaard is, diuretika gebruik (waterpille) of gedehidreer is.
- Jou dokter sal jou cholesterolvlakke gereeld monitor, aangesien **VEXALIN XR** die cholesterolvlakke in jou bloed kan verhoog.
- Indien jou dokter dink dat jy nie meer **VEXALIN XR** nodig het nie, kan hy/sy jou vra om jou dosering stadig te verminder voordat jy heeltemal ophou. Dit is bekend dat newe-effekte voorkom wanneer mense ophou met die gebruik van **VEXALIN XR**, veral as **VEXALIN XR** skielik gestaak word of die dosering te vinnig verminder word (sien MOONTLIKE NEWE-EFFEKTE).
- **VEXALIN XR** kan simptome van seksuele disfunksie veroorsaak. In sommige gevalle het hierdie simptome voortgeduur nadat behandeling gestaak is.
- **VEXALIN XR** kan 'n gevoel van onrustigheid of 'n onvermoë veroorsaak om stil te sit of stil te staan gedurende die eerste paar weke van die behandeling. Jy moet jou dokter vertel indien dit met jou gebeur.
- **VEXALIN XR** kan 'n droë mond veroorsaak. Neem spesiale sorg met jou tandhigiëne, aangesien 'n droë mond die risiko van tandbederf kan verhoog.
- Jou bloedglukosevlakke kan verander as gevolg van **VEXALIN XR**. Daarom moet die dosis van jou diabetes medisyne aangepas word.
- Dit is onwaarskynlik dat jy verdraagsaamheid sal ontwikkel of verslaaf sal raak aan **VEXALIN XR** indien jy dit oor 'n lang tydperk neem, maar jou dokter sal egter jou behandeling monitor vir tekens van verdraagsaamheid of verslawing.
- **VEXALIN XR** kan met veiligheid gebruik word in gesonde bejaarde pasiënte.

**Kinders en adolessente**
- **VEXALIN XR** moet nie aan kinders jonger as 18 jaar oud gegee word nie, aangesien daar nie bewys is dat dit veilig en effektief in hierdie ouderdomsgroep is nie.

**Ander medisyne en VEXALIN XR**
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Neem slegs ander medisyne, terwyl jy **VEXALIN XR** gebruik, indien jou dokter sê dat jy kan.
Jy moet jou dokter vertel indien jy die volgende medisyne gebruik:
- Monoamienoksidase-inhibeerders (MAOIs) soos moklobemied ('n antidepressant) en linesolied ('n antibiotikum).
- Medisyne om depressie te behandel, byvoorbeeld medisyne bekend as SNHI's of SSHI's en medisyne wat litium bevat.
- Medisyne wat die vlak van serotonien verhoog: Triptane, tramadol, triptofaan, SSHI's (soos paroksetien en fluoksetien), SNHI's (soos venlafaksien), trisikliese antidepressante (soos klomipramien, amitriptllien), petidien, Sint-Janskruid (kruiemedisyne vir depressie) en MAOIs (soos moklobemied en linesolied). Hierdie medisyne verhoog die risiko van newe-effekte; indien jy ongewone simptome ervaar terwyl jy enige van hierdie medisyne saam met **VEXALIN XR** inneem, moet jy jou dokter besoek.
- Aanvullings wat triptofaan bevat (word gebruik vir probleme soos slaap en depressie).
- Indinavir (vir MIV behandeling)
- Desipramien (vir depressie)
- Sibutramien (gebruik vir gewigsverlies).
- Ketokonasool ('n antifungusmiddel).
- Haloperidol of risperidoon (om psigiatriese kondisies te behandel)
- Metoprolol ('n betablokker vir die behandeling van hoë bloeddruk en hartprobleme)
- Medisyne wat jou hartritme kan beïnvloed. Voorbeelde van hierdie medisyne sluit in:
  - Antidisritmiese middels soos kinidien, amiodaroon, sotalol of dofetilied (word gebruik om abnormale hartritme te behandel)
  - Antipsigotika soos tioridasien (sien ook Serotonien-sindroom hierbo)
  - Antibiotika soos eritromisien of moksifloksasien (gebruik vir die behandeling van bakteriële infeksies)
  - Antihistamiene (word gebruik om allergieë te behandel).

Stel jou dokter in kennis dat jy **VEXALIN XR** neem wanneer bloedtoetse benodig word om te toets vir fensiklidien (PCP) of amfetamien.

**VEXALIN XR met voedsel en drankies en alkohol**
Alkohol moet vermy word tydens behandeling met **VEXALIN XR**.

**Swangerskap, borsvoeding en fertiliteit**
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies voordat jy **VEXALIN XR** neem.
- Vertel jou dokter as jy swanger raak, of as jy probeer om swanger te raak, terwyl jy **VEXALIN XR** gebruik. Jy moet nie **VEXALIN XR** neem as jy swanger is nie.
- Indien jy **VEXALIN XR** teen die einde van jou swangerskap neem, kan jou baba sommige simptome hê wanneer hy gebore word. Dit begin gewoonlik met die geboorte of binne 'n paar dae nadat jou baba gebore is. Hierdie simptome kan nie behoorlike voeding, probleme met asemhaling en langdurige hospitalisasie insluit.
- Vertel jou dokter as jy borsvoed. Jy moet nie **VEXALIN XR** neem tydens borsvoeding nie.

**Bestuur en gebruik van masjinerie**
**VEXALIN XR** kan inkorting van oordeel, denke of spierbeheer veroorsaak. Dit is nie altyd moontlik om te voorspel tot watter mate **VEXALIN XR** jou daaglikse aktiwiteite kan beïnvloed nie. Jy moet nie aan bogenoemde aktiwiteite deelneem nie, totdat jy bewus is van die mate waarin **VEXALIN XR** jou beïnvloed.

## 3. Hoe om VEXALIN XR te neem

- Moet nie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
- Neem altyd **VEXALIN XR** presies soos jou dokter of apteker jou vertel het. Vra jou dokter of apteker indien jy onseker is.
- Jou dokter sal jou presies vertel hoe lank jou behandeling met **VEXALIN XR** sal duur. Moet nie die behandeling vroeër stop nie.
- Indien jy onder die indruk is dat die effek van **VEXALIN XR** te sterk of te swak is, praat dan met jou dokter of apteker.
- Bly onder die sorg van 'n gesondheidsorgverskaffer wanneer jy **VEXALIN XR** gebruik. Moet nie jou behandeling verander of stop sonder om eers met jou gesondheidsorgverskaffer te praat nie.

**Aanbevole VEXALIN XR dosis:**
- **VEXALIN XR** kapsules is vir mondelinge gebruik.
- Jou dokter sal jou vertel hoeveel **VEXALIN XR** om te neem en vir hoe lank jy moet aanhou om dit te neem.
- Die normale aanbevole aanvangsdosis vir behandeling van depressie, algemene angsversteuring en sosiale angsversteuring is 75 mg per dag. Die dosering kan geleidelik deur jou dokter verhoog word, en indien nodig, selfs tot 'n maksimum dosis van 375 mg per dag vir depressie. Die maksimum dosering vir algemene angsversteuring en sosiale angsversteuring is 225 mg/dag.
- Neem **VEXALIN XR** elke dag op ongeveer dieselfde tyd, hetsy soggens of saans. Kapsules moet heel met vloeistof ingesluk word en nie oopgemaak, fyngedruk, gekou of opgelos word nie. **VEXALIN XR** moet saam met voedsel geneem word.
- As jy lewer- of nierprobleme het, sal jou dokter jou **VEXALIN XR** dosis aanpas.
- Moet nie bekommerd wees indien jy klein wit korreltjies of deeltjies in jou stoelgang sien nadat jy **VEXALIN XR** geneem het nie. **VEXALIN XR** formule bevat sferoïede wat die medisyne stadig in die spysverteringskanaal vrystel. Die onoplosbare gedeelte van hierdie sferoïede word uitgeskakel en kan in ontlasting gesien word.

**As jy meer VEXALIN XR neem as wat jy moet**
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Die simptome van 'n moontlike oordosering kan vinnige hartklop, veranderinge in die vlak van waaksaamheid (wat wissel van slaperigheid tot koma), dowwe sig, aanvalle of stuiptrekkings, en braking insluit.

**Indien jy vergeet om VEXALIN XR te neem**
Indien jy vergeet om 'n dosis te neem, neem dit sodra jy daarvan onthou, en gaan dan aan soos voorheen. Moet nie 'n dubbele dosis neem om vir die vergete individuele dosisse op te maak nie.

**As jy ophou om VEXALIN XR te neem**
Moet nie ophou om jou kapsules te neem net omdat jy beter voel nie. Dit is belangrik dat jy aanhou om **VEXALIN XR** te neem vir so lank as wat jou dokter jou sê.
Indien jou dokter dink dat jy nie meer **VEXALIN XR** nodig het nie, kan hy/sy jou vra om jou dosering stadig te verminder voordat jy heeltemal daarmee ophou. Nadat jy lang- en kort termyn behandeling met **VEXALIN XR** gestaak het, moet jy weet dat jy sekere newe-effekte kan ervaar. Sommige pasiënte kan simptome ervaar soos buierigheid, angs, rusteloosheid, senuweeagtigheid, verwarring, slapeloosheid of ander slaapsteurnisse, moegheid, slaperigheid, tinteling, duiseligheid, aanvalle, draai sensasie (vertigo), hoofpyn, griepagtige simptome, suis in die ore (tinnitus), ingekorte koördinasie en balans, bewing, sweet, droë mond, verlies aan eetlus, diaree, naarheid en braking.
Jou dokter sal jou adviseer oor hoe jy die behandeling met **VEXALIN XR** geleidelik moet staak. Vra jou dokter vir verdere advies as jy enige van hierdie of ander simptome ervaar wat jou pla.

## 4. Moontlike newe-effekte

**VEXALIN XR** kan newe-effekte hê.
Nie alle newe-effkete wat vir **VEXALIN XR** aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid versleg of indien jy enige ongunstige effekte ervaar terwyl jy **VEXALIN XR** neem, kontak asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.
Indien enige van die volgende gebeur, hou op om **VEXALIN XR** te neem, en kontak jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal:
Vra nood mediese hulp as jy enige van die hierdie **tekens van 'n allergiese reaksie het**:
- Galbulte; kortasem of asemhalingsprobleme; swelling van jou gesig, lippe, tong of keel.

Hierdie is almal baie ernstige newe-effekte. As jy dit het, het jy moontlik 'n ernstige allergiese reaksie op **VEXALIN XR** gehad. Jy benodig moontlik dringende mediese hulp of hospitalisasie.

Vertel dadelik jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- Voel gedehidreerd, het lae vlakke natrium in die bloed (meestal in bejaardes; die simptome kan insluit dat jy duiselig, swak, verward, slaperig of baie moeg, of siek voel, ernstiger simptome is flou word, aanvalle of valle), waterretensie deur die liggaam (sindroom van onvanpaste afskeiding van antidiuretiese hormoon (SOADH)).
- Indien jy aanvalle het (stuiptrekkings).
- Gedagtes van selfmoord en selfbeskadiging.
- Serotoniensindroom, 'n potensieel lewensbedreigende toestand kan voorkom met **VEXALIN XR** behandeling. Stel jou dokter in kennis of gaan na die naaste hospitaal as jy 'n kombinasie van die volgende waarneem: rusteloosheid, hallusinasies, verlies aan koördinasie, vinnige hartklop, verhoogde liggaamstemperatuur, verandering in bloeddruk, ooraktiewe reflekse, diaree, naarheid, braking en koma.
- In sy ernstigste vorm kan serotoniensindroom lyk soos Neuroleptiese Maligne Sindroom (NMS). Tekens en simptome van NMS kan insluit 'n kombinasie van koors, vinnige hartklop, sweet, ernstige spierstyfheid, verwarring, verhoogde spierensieme (bepaal deur 'n bloedtoets).
- Simptome van rabdomiolise (afbreek van spierweefsel): donker, rooi of kola kleurige uriene, verminderde urienuitset, algemene swakheid, spierstyfheid of pyn, spierteerheid, swakheid van die aangetaste spiere.
- Vinnige en/of onreëlmatige hartklop of abnormale vinnige hartklop, veranderinge op die EKG verwys na 'n verlenging van die QT-interval, d.w.s., vertraagde geleiding van elektriese seine.
- Hoes, asemgefluit, kortasem en 'n hoë temperatuur, wat simptome is van inflammasie in die longe wat gepaard gaan met die toename in witbloedselle (pulmonale eosinofilie).
- Braking van bloed, of swart teeragtige stoelgang (ontlasting).
- Ontsteking van die pankreas met simptome, insluitend boonste buikpyn, naarheid en braking.
- Inflammasie van die lewer of lewerversaking wat buikpyn en vergeling van die vel of wit van die oë (geelsug) kan veroorsaak.
- Stevens-Johnson-sindroom (ernstige siekte met blase wat vorm op die vel, mond, oë en geslagsdele).
- Erge veluitslag, jeuk of netelroos (verhewe kolle van rooi- of bleek vel wat dikwels jeuk)
- Langdurige bloeding - as jy jouself sny of beseer, kan dit langer neem as gewoonlik voordat bloeding stop.
- Sametrekking van die kaakspier (kaakklem).

Hierdie is almal baie ernstige newe-effekte. Jy benodig moontlik dringende mediese aandag.

Vertel jou dokter indien jy enige van die volgende opmerk:
*Algemene newe-effekte:*
- ongewone drome, verminderde seksdrang, slaapprobleme, senuweeagtigheid
- duiseligheid, droë mond, traagheid, gevoelloosheid, insluitend gevoelloosheid, prikkelende of tintelende vel, voel slaperig, bewing, veranderde of ingekorte smaaksensasie.
- oogprobleme soos dowwe sig, verwyde pupille, onvermoë van die oog om outomaties fokus te verander vanaf ver na naby voorwerpe,
- tinnitus (geluid in die oor as daar geen eksterne geluid is nie)
- verhoogde bloeddruk, blosing
- gaap meer, probleme met asemhaling
- verminderde eetlus, siek gevoel (naarheid), hardlywigheid, siek wees (braking)
- probleme met urinering
- probleme om 'n ereksie te kry, veranderinge in ejakulasie/orgasme in mans
- swakheid, moegheid, pyn, maagpyn, rugpyn, borskaspyn.

*Minder algemene newe-effekte:*
- kneusing van die vel
- voel onverskillig, hallusinasies, psigiatriese probleme, soos hiperaktiwiteit en voel ongewoon meer as opgewonde
- skielike onwillekeurige rukke of trekke van die spiere
- probleme met slaap, voel gedisoriënteerd, gebrek aan motivering
- flou word, lighoofdigheid of floute wanneer opstaan
- ontsteking van die dikderm (wat lei tot diaree), winde opbreek, sukkel om te sluk, ontsteking van die mond, slegte asem
- veluitslag, sensitiwiteit vir sonlig
- probleme met, of onvermoë om te kan urineer
- abnormale orgasme in vrouens
- voel koud of warm, dors, sidder, voel sleg, abnormale stap
- gewig optel
- veranderinge in bloedtoetsresultate (vermindering in natrium in die bloed, afname in die aantal witbloedselle, verhoogde bloedsuiker, vermindering van aantal bloedplaatjies, gewigstoename, gewigsvermindering, lewerensieme verhoog.

*Newe-effekte waarvan die frekwensie nie bekend is nie:*
- bloeiende tandvleise
- verminderde aantal bloedplaatjies in jou bloed, wat lei tot 'n verhoogde risiko vir kneusing of bloeding
- tekens van infeksie, soos hoë temperatuur, kouekoors, rilling, hoofpyne, sweet, griepagtige simptome. Dit kan die gevolg wees van 'n bloedversteuring (vermindering van sekere witbloedselle) wat lei tot 'n verhoogde risiko vir infeksie.
- verhoogde prolaktienvlakke in die bloed (abnormale produksie van borsmelk)
- verwarring; voel geskei, (of losstaande) van jouself, rusteloosheid, disoriëntasie en verwarring dikwels gepaard met hallusinasie (delirium), aggressie, geheueverlies, angs, depressie, gebrek aan gevoel of emosie; abnormale denke, onvanpaste gedrag
- hoofpyn, probleme om beweging te beheer bv. gebrek aan koördinasie of onwillekeurige bewegings van die spiere, spierstyfheid, gevoel van rusteloosheid of 'n onvermoë om stil te sit of stil te staan, herhalende, onwillekeurige bewegings soos mondtrekkings en oogknip, gevoelloosheid of 'n verminderde gevoel van aanraking, swak slaapkwaliteit
- verhoogde druk in die oë (gloukoom)
- vertigo (draai sensasie)
- voel hoe die hart in die borskas pomp.
- lae bloeddruk
- seerkeel, loop- of toe neus
- die tande slyp of kners, verhoogde eetlus, diaree, sooibrand of slegte spysvertering, winde opbreek, winde laat
- spierpyn, spierspasma
- sweet (insluitend nagsweet), netelroos, jeukerige veluitslag, abnormale haarverlies
- nodig om meer te urineer as normaal
- menstruele afwykings wat verband hou met verhoogde bloeding of verhoogde ongereelde bloeding, bloeding (swaar bloeding) nadat geboorte gegee is.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, moet jy jou dokter of apteker daarvan in kennis stel.

**Aanmelding van newe-effekte**
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in, wat nie in hierdie inligtingsblad gelys is nie. Jy kan ook newe-effekte aanmeld by SAHPRA via die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **VEXALIN XR** te voorsien.

## 5. Hoe om VEXALIN XR te berg

Bewaar by of benede 25°C.
Beskerm teen lig en vog.
Bewaar die stulpstrook in die karton totdat dit benodig word vir gebruik.
Hou die HDPE houers dig gesluit.
HOU BUITE BEREIK VAN KINDERS.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum wat aangebring is op die etiket/karton/bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in die riool of rioolstelsel (bv. toilette) gooi nie.

## 6. Inhoud van die pak en ander inligting

**Wat VEXALIN XR bevat**
- Die aktiewe bestanddeel is venlafaksienhidrochloried 75 mg/150 mg.
- Die ander bestanddele is lae gesubstitueerde hidroksiepropielsellulose, mieliestysel, mikrokristallyne sellulose, etielsellulose, hidroksipropielmetielsellulose, gesuiwerde talkpoeier, harde gelatien kapsules wat titaandioksied bevat, rooi ysteroksied, gelatien en natriumlaurielsulfaat. Daarbenewens bevat **VEXALIN XR 75 mg** geel ysteroksied.

**Hoe VEXALIN XR lyk en die inhoud van die pak**
**VEXALIN XR 75 mg** (Verlengde-vrystellings kapsules)
Wit tot afwit verlengde-vrystelling krale, gevul in grootte '1' kapsules met 'n perske doppie/perske liggaam, met 'L 87' op doppie en '75' op liggaam gedruk met rooi ink.
**VEXALIN XR 150 mg** (Verlengde-vrystellings kapsules)
Wit tot afwit verlengde-vrystellings krale, gevul in grootte '0el' kapsules met donker oranje doppie/donker oranje liggaam, met 'L 88' op doppie en '150' op liggaam gedruk met wit ink.

**Stulpverpakking:**
Gewone, silwergekleurde, 25 µ aluminium foelie/ 6-8 gsm HSL as die dekmateriaal en helder, deursigtige PVC/PE/PVdC, 250 µ/25 µ/90 gsm, as die vormingsmateriaal, verpak in 'n voorafgedrukte eenheidskarton met 10, 28 of 30 kapsules.
**HDPE houer verpakking:**
Kapsules is verpak in 'n wit, ondeursigtige, ronde 40 ml of 60 ml HDPE houer vir **VEXALIN XR 75** mg en 60 ml HDPE houer vir **VEXALIN XR 150 mg** met 33 mm nekafwerking, gesluit met 33 mm wit polipropileen sluiting met waad en induksie-sluitingvoering. Elke houer bevat 28 of 30 kapsules met 'n silika gel. Die houers word geplaas in 'n voorafgedrukte buitenste karton met 'n inligtingsblad.

**Houer van die Sertifikaat van Registrasie en Vervaardiger**
**MACLEODS PHARMACEUTICALS SA (Edms) Bpk**
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Rylaan 1, Bassonia Rock, Uitbreiding 12,
Alberton, Suid Afrika

**Hierdie inligtingsblad is laas hersien in:**
20 April 2021

**Registrasienommer**
**VEXALIN XR 75 mg** (Verlengde-vrystellings kapsules): 51/1.2/0059.057
**VEXALIN XR 150 mg** (Verlengde-vrystellings kapsules): 51/1.2/0060.058

**Toegang tot die ooreenstemmende Professionele Inligting**
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

PACKAGING RESEARCH & DEVELOPMENT

*Restricted Circulation*

**(Front Page)**

# ARTWORK / PRINTPROOF APPROVAL FORM

**Note : Exclude Professional Information and dimension change.**

| | |
|---|---|
| **1. Product: VEXALIN XR ( Venlafaxine hydrochloride capsule )** | |
| **2. Country: South Africa (Private Market)** | **3. Packaging component: Patient Information Leaflet** |
| **4. No. of Colours: 1 Colour** | **5. Pantone Shade No.: Black** |
| **6. Specification: 40 gsm bible paper** | |
| **7. Machine Layout No.: NA** | **8. Dimensions: 535 (L) x 400 (W) mm** |
| **9. Design / Style: Booklet Type** | **10. Item code No.: PM03930102** |
| **11. Artwork has been made: Actual Size** | **12. Pharma code No.: 33943 mini** |
| **13. Barcode/NDC no: NA** | **14. Supersedes Item code No: PM03930101** |
| **15. Revision no: 01** | **16. A/W File name:Z:\Venlafaxin Capsule\SA private Market\02\VENLAFAXINE 75 MG PI & PIL - PM03930102.cdr** |
| **Approved By:** | **17. Location: Baddi** |

| PRD | M.A. HOLDER | RAD | QC | PRODN | QA |
|---|---|---|---|---|---|
| | Vanita Rajool Digitally signed by Vanita Rajool DN: cn=Vanita Rajool, o=Macleods Pharmaceuticals SA (Pty) Ltd., ou=Responsible Pharmacist, email=vanitar@macleodspharma.com , c=ZA Date: 2024.08.06 10:31:16 +02'00' | | | | |

**Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.**

**Instructions to Vendor** :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

**FRM/CQA/021/04-01**

| Reason for revision : | Item code | Artwork Send for Printing Date | Artwork Implementation Date |
|---|---|---|---|
| 1) New Artwork for South Africa (Private Market) | PM03930101 | 11/01/23 | 11/02/23 |
| 2) Exclude Professional Information and dimension change. | PM03930101 | | |