SCHEDULING STATUS: S5

Venlafaxine XR 37,5 Adco, 37,5 mg, extended-release capsules
Venlafaxine XR 75 Adco, 75 mg, extended-release capsules
Venlafaxine XR 150 Adco, 150 mg, extended-release capsules
Venlafaxine XR 225 Adco, 225 mg, extended-release capsules

Venlafaxine hydrochloride equivalent to venlafaxine
Venlafaxine XR Adco is sugar free

Read all of this leaflet carefully before you start taking Venlafaxine XR Adco

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

1. What Venlafaxine XR Adco is and what it is used for

Venlafaxine XR Adco is an antidepressant that belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). This group of medicines is used to treat depression and other conditions such as anxiety disorders. It is thought that people who are depressed and/or anxious have lower levels of serotonin and noradrenaline in the brain. It is not fully understood how antidepressants work, but they may help by increasing the levels of serotonin and noradrenaline in the brain.

Venlafaxine XR Adco is used to treat adults with depression, including depression associated with anxiety (feeling of worry or nervousness). Venlafaxine XR Adco is also used to treat

severe and persistent anxiety (known as generalised anxiety disorder), social anxiety disorder also known as social phobia (fear or avoidance of social situations).
Treating depression or anxiety disorders properly is important to help you get better. If it is not treated, your condition may not go away and may become more serious and more difficult to treat.
Venlafaxine XR Adco is used to prevent a relapse of an episode of depression or to prevent recurrence and your doctor will periodically re-evaluate you.

2. What you need to know before you take Venlafaxine XR Adco

Do not take Venlafaxine XR Adco:

- if you are hypersensitive (allergic) to venlafaxine or to any of the other ingredients of Venlafaxine XR Adco (listed in section 6)
- if you are taking monoamine oxidase inhibitors (MAOI's), a medicine also used to treat depression or Parkinson's disease, or have taken it in the last 14 days (also, you must wait at least 7 days after you stop taking Venlafaxine XR Adco before you take any MAOI)
- if you are under the age of 18
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with Venlafaxine XR Adco:

- If you use other medicines that taken together with Venlafaxine XR Adco could increase the risk of developing serotonin syndrome (see the section "Other medicines and Venlafaxine XR Adco").
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- If you have a history of high blood pressure.
- If you have a history of heart problems.
- if you have a history of myocardial infarction or unstable heart disease.
- If you have a history of fits (seizures).
- If you have a history of low sodium levels in your blood (hyponatraemia).
- If you have a tendency to develop bruises or a tendency to bleed easily (history of bleeding disorders), or if you are taking other medicines that may increase the risk of bleeding e.g., warfarin (used to prevent blood clots).
- If you are pregnant as there may be an increased risk of heavy vaginal bleeding shortly after birth (see 'Pregnancy' and 'Do not take Venlafaxine XR Adco').
- If you have a history of high cholesterol.

- If you are taking weight loss medicines.
- If you have a history of, or if someone in your family has had, mania or bipolar disorder (feeling over-excited or euphoric).
- If you have a history of aggressive behaviour.
- If you need to have screening tests for phencyclidine and amphetamine.

Thoughts of suicide and worsening of your depression or anxiety disorder
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, since these medicines all take time to work, usually about two weeks, but sometimes longer.

You may be more likely to think like this:
- If you have previously had thoughts about killing yourself or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

Dry mouth
Venlafaxine XR Adco may cause a dry mouth, this may increase the risk of caries and dental hygiene is very important.

Diabetes
Your blood glucose levels may be altered due to Venlafaxine XR Adco. Therefore, the dosage of your diabetes medicines may need to be adjusted.

Sexual problems
Venlafaxine XR Adco (so called SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Talk to your doctor before taking Venlafaxine XR Adco, especially if you have:
- History of bleeding disorders, or if you are pregnant (see ‘Pregnancy’)

Children and adolescents
Do not give Venlafaxine XR Adco to children and adolescents under the age of 18 years. Suicide-related behaviours (suicide attempt and suicidal thoughts) and anger (predominantly

aggression, oppositional behaviour and anger) were more frequently observed among children and adolescents.

Other medicines and Venlafaxine XR Adco

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

You should tell your doctor if you are using the following medicines:

- Monoamine Oxidase Inhibitors (MOAI) which are used to treat depression or Parkinson's disease must not be taken with Venlafaxine XR Adco. Tell your doctor if you have taken these medicines within the last 14 days (MAOIs: see the section What you need to know before you take Venlafaxine XR Adco).
- **Serotonin syndrome:**

A potentially life-threatening condition or Neuroleptic Malignant Syndrome (NMS)-like reactions (see the section "Possible Side Effects") may occur with Venlafaxine XR Adco 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 sibutramine (used for weight loss)
- Medicines containing tramadol, fentanyl, tapentadol, pethidine, or pentazocine (used to treat severe pain)
- Medicines containing linezolid, an antibiotic (used to treat infections)
- Medicines containing moclobemide, a MAOI (used to treat depression)
- 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)

Signs and symptoms of serotonin syndrome may include a combination of the following: restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting.

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).

Tell your doctor immediately or go to the casualty department at your nearest hospital if you experience any of the above symptoms.

You must tell your doctor if you are taking medicines that can affect your heart rhythm such as:

- Anti-dysrhythmics 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)

The following medicines may also interact with Venlafaxine XR Adco and should be used with caution. It is especially important to mention to your doctor or pharmacist if you are taking medicines containing:

- Ketoconazole (an antifungal medicine)
- Cimetidine (an antacid), especially if you are elderly or have liver problems
- Imipramine, bupropion or fluoxetine (antidepressants)
- Ritonavir (an antiretroviral used for HIV/AIDS)
- Haloperidol or risperidone (to treat psychiatric conditions)
- Metoprolol (a beta blocker to treat high blood pressure and heart problems)

Venlafaxine XR Adco with food and alcohol

You should not take any alcohol when taking Venlafaxine XR Adco.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking Venlafaxine XR Adco.

Pregnancy
Do not take Venlafaxine XR Adco if you are pregnant.
If your baby was exposed to Venlafaxine XR Adco late in the third trimester, your baby might have symptoms of not feeding properly when born. If your baby has these symptoms when it is born and you are concerned, contact your doctor and/or midwife who will be able to advise you.

If you take Venlafaxine XR Adco near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Venlafaxine XR Adco so they can advise you.

Breastfeeding
Venlafaxine XR Adco is excreted in breast milk, therefore, mothers who breastfeed their babies should not take Venlafaxine XR Adco.

Driving and using machines
Venlafaxine XR Adco may cause you to feel dizzy and sleepy which may therefore impair your judgement, thinking and motor skills.

It is not always possible to predict to what extent Venlafaxine XR Adco may interfere with your daily activities. Do not engage in driving a vehicle or using machines until you are aware of the measure to which Venlafaxine XR Adco affects you.

Venlafaxine XR 150 Adco contains Allura Red AC (E129) and Sunset Yellow FCF (E110)
Allura Red AC (E129) and Sunset Yellow FCF (E110) may cause allergic reactions.

Venlafaxine XR 225 Adco contains the colourant Carmoisine (E122)
Carmoisine (E122) may cause allergic reactions.

3. How to take Venlafaxine XR Adco
Do not share medicines prescribed for you with any other person.
Always take Venlafaxine XR Adco exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual recommended starting dose for Venlafaxine XR Adco 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, social anxiety disorder and panic disorder is 225 mg/day.

Swallow the capsule whole with fluid. Do not divide, crush, chew or place capsule in water.

Take Venlafaxine XR Adco once daily at the same time either in the morning or in the evening.

Venlafaxine XR Adco should be taken with food.

If you have liver or kidney problems, talk to your doctor, since your dose of Venlafaxine XR Adco may need to be different.
Your doctor will frequently assess if you need to be on long-term therapy with Venlafaxine XR Adco.
Your doctor will tell you how long your treatment with Venlafaxine XR Adco will last. Do not stop treatment early because you feel better. If you have the impression that the effect of Venlafaxine XR Adco is too strong or too weak, tell your doctor or pharmacist.

If you take more Venlafaxine XR Adco than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison 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 Venlafaxine XR Adco
Do not take a double dose to make up for forgotten individual doses.

If you stop taking Venlafaxine XR Adco
Do not stop taking your treatment or reduce the dose without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need Venlafaxine XR Adco, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop using Venlafaxine XR Adco, especially when it is stopped suddenly, or the dose is reduced too quickly. Some patients may experience symptoms such as tiredness, dizziness, light-headedness, headache, sleeplessness, nightmares, dry mouth, loss of appetite, nausea, diarrhoea, nervousness, agitation, confusion, ringing in the ears, tingling or rarely electric shock sensations, weakness, sweating, seizures, or flu-like symptoms.

Your doctor will advise you on how you should gradually discontinue Venlafaxine XR Adco treatment. If you experience any of these or other symptoms that are troublesome, ask your doctor for further advice.

4. Possible side effects

Venlafaxine XR Adco can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Venlafaxine XR Adco. 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:

- Heart problems, such as fast or irregular heart rate, increased blood pressure.
- Chest tightness, wheezing, trouble swallowing or breathing.
- Severe skin rash, itching or hives (elevated patches of red or pale skin that often itch).
- Signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting.

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).

- Signs of infection, such as high temperature, chills, shivering, headaches, sweating, flu-like symptoms. This may be the result of a blood disorder which leads to an increased risk of infection.
- Severe rash, which may lead to severe blistering and peeling of the skin.
- Unexplained muscle pain, tenderness or weakness. This may be a sign of rhabdomyolysis.

- Thoughts of harming or killing yourself.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- decreased appetite
- difficulty sleeping
- abnormal dreams, nervousness
- decreased libido, abnormal ejaculation/orgasm (males)
- dizziness, drowsiness, shaking
- paraesthesia (abnormal sensation, typically tingling or pricking)
- altered taste
- blurred vision, dilated pupils, vision loss, inability of the eye to automatically change focus from distant to near objects
- hot flushes
- yawning
- nausea, dry mouth, constipation, vomiting, stomach pain
- an abnormally high level of muscle tone or tension, back pain
- inability to pass urine; difficulties passing urine
- impotence
- tiredness, lack of energy, pain
- weight gain, weight loss
- increased cholesterol

Less frequent side effects:

- over activity, racing thoughts and decreased need for sleep (mania)
- feeling over-excited (hypomania)
- hallucinations
- derealisation (feeling that one’s surroundings are not real), apathy (lack of interest)
- abnormal orgasm
- involuntary muscle jerks or twitches; fits
- feeling dizzy (particularly when standing up too quickly)
- sensitivity to sunlight; bruising

Frequency unknown:

- sensation of whirling and loss of balance

- blood disorders such as granulocytes in the blood, deficiency of all types of blood cell caused by failure of bone marrow development, red cells, white cells, and platelets deficiency (pancytopaenia), platelets deficiency in the blood (thrombocytopaenia) (will be determined by a blood test)
- excessive water retention (known as SIADH)
- abnormal breast milk production
- decrease in blood sodium levels
- increased appetite
- confusion, feeling separated (or detached) from yourself
- agitation
- grinding of teeth (especially during sleep)
- headache
- a sensation of restlessness or an inability to sit or stand still
- involuntary movements of the muscles
- balance disorder
- muscular spasm and abnormal posture
- angle-closure glaucoma
- ringing in the ears
- low blood pressure
- inflammation of the lungs
- coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- sore throat, runny nose, sneezing
- vomiting blood, black tarry stools (faeces) or blood in stools which can be signs of bleeding in the gastrointestinal tract
- severe abdominal or back pains, feeling sick and vomiting which could indicate inflammation of the pancreas
- diarrhoea
- severe weight loss (anorexia)
- indigestion, burping, wind (flatulence)
- increased liver function tests (determined by a blood test)
- itchiness, yellow skin or eyes, dark urine, or flu-like symptoms, which are symptoms of inflammation of the liver (hepatitis)
- excessive sweating (including night sweats)
- hives, hair loss, swelling of the legs and arms
- bulging, rash-like lesion that is red, pink, purple, or brown

- muscle pain
- increased frequency in urination
- involuntary leakage of urine
- menstrual irregularities such as increased bleeding or increased irregular bleeding
- chills
- unexpected bleeding, e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins)
- extended bleeding - if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Venlafaxine XR Adco.

5. How to store Venlafaxine XR Adco

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C. Store in original packaging until required for use.

Protect from light and moisture. Keep HDPE containers tightly closed.

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 Venlafaxine XR Adco contains

Venlafaxine XR 37,5 Adco: The active substance is venlafaxine hydrochloride equivalent to 37,5 mg venlafaxine free base.

The other ingredients are:

Capsule contents (mini tablets):

Core: microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, povidone, talc.

Film coating: copovidone, ethyl cellulose.

Capsule shell: gelatine, iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), titanium dioxide (E171), purified water.

Capsule printing ink: butyl alcohol, dehydrated alcohol (E1510), isopropyl alcohol, propylene glycol (E1520), shellac (E904), concentrated ammonia solution (E527), iron oxide red (E172).

Venlafaxine XR 75 Adco: The active substance is venlafaxine hydrochloride equivalent to 75 mg venlafaxine free base.
The other ingredients are:
Capsule contents (mini tablets):
Core: microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, povidone, talc.
Film coating: copovidone, ethyl cellulose.
Capsule shell: gelatine, iron oxide black (E172), iron oxide red (E172), titanium dioxide (E171), purified water.
Capsule printing ink: butyl alcohol, dehydrated alcohol (E1510), isopropyl alcohol, propylene glycol (E1520), shellac (E904), concentrated ammonia solution (E527), iron oxide red (E172).

Venlafaxine XR 150 Adco: The active substance is venlafaxine hydrochloride equivalent to 150 mg venlafaxine free base.
The other ingredients are:
Capsule contents (mini tablets):
Core: microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, povidone, talc.
Film coating: copovidone, ethyl cellulose.
Capsule shell: gelatine, Brilliant Blue FCF (E133), Allura Red AC (E129), Sunset Yellow FCF (E110), titanium dioxide (E171), purified water.
Capsule printing ink: butyl alcohol, dehydrated alcohol (E1510), isopropyl alcohol, propylene glycol (E1520), shellac (E904), sodium hydroxide, povidone, titanium dioxide (E171).

Venlafaxine XR 225 Adco: The active substance is venlafaxine hydrochloride equivalent to 225 mg venlafaxine free base.
The other ingredients are:
Capsule contents (mini tablets):
Core: microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, povidone, talc.
Film coating: copovidone, ethyl cellulose.
Capsule shell: Carmoisine (E122), gelatine, titanium dioxide (E171), purified water.
Capsule printing ink: butyl alcohol, dehydrated alcohol (E1510), isopropyl alcohol, propylene glycol (E1520), shellac (E904), concentrated ammonia solution (E527), Indigo Carmine (E132) lake.

What Venlafaxine XR Adco looks like and contents of the pack

Venlafaxine XR 37,5 Adco is a light grey opaque / peach opaque size “3” hard gelatine capsule having thick and thin radial circular bands on the body in red ink and thick and thin radial circular bands on the cap in red ink, filled with white to off white, round, biconvex, film-coated mini tablets.

Venlafaxine XR 75 Adco is a peach opaque / peach opaque size “1” hard gelatine capsule having thick and thin radial circular bands on the body in red ink and thick and thin radial circular bands on the cap in red ink, filled with white to off white, round, biconvex, film-coated mini tablets.

Venlafaxine XR 150 Adco is a dark orange / dark orange opaque size “0” hard gelatine capsule having thick and thin radial circular bands on the body in white ink and thick and thin radial circular bands on the cap in white ink, filled with white to off white, round, biconvex, film-coated mini tablets.

Venlafaxine XR 225 Adco is a pink opaque / pink opaque, size ”00” hard gelatine capsule having thick and thin radial circular bands on the body in blue ink and thick and thin radial circular band on the cap in blue ink filled with mini tablets.

Venlafaxine XR Adco extended-release capsules are packed in:

- Aluminium/aluminium foil blister strips (only for the 225 mg capsules)
- Aluminium foil and white opaque PVC-Aclar film blister strips
- Aluminium foil and white opaque PVC-PVdC film blister strips
- White HDPE containers with child resistant cap, and an absorbent cotton (only for the 37,5 mg, 75 mg and 150 mg capsules)

Pack sizes: 10 or 14 capsules per blister strip in a pack of 10, 14, 28, 30 or 100 capsules in an outer carton along with professional information and/or patient information leaflet. 30, 100, 500 or 1 000 capsules per HDPE container.
Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Customer Care: 0860 ADCOCK / 232625

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Venlafaxine XR 37,5 Adco:	43/1.2/0577
Venlafaxine XR 75 Adco:	43/1.2/0578
Venlafaxine XR 150 Adco:	43/1.2/0579
Venlafaxine XR 225 Adco:	52/1.2/0438

PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: S5

Venlafaxine XR 37,5 Adco, 37,5 mg, verlengde-vrystelling kapsules
Venlafaxine XR 75 Adco, 75 mg, verlengde-vrystelling kapsules
Venlafaxine XR 150 Adco, 150 mg, verlengde-vrystelling kapsules
Venlafaxine XR 225 Adco, 225 mg, verlengde-vrystelling kapsules

Venlafaksienhidrochloried gelykstaande aan venlafaksien
Venlafaxine XR Adco is suikervry

Lees hierdie hele biljet noukeurig deur voordat u Venlafaxine XR Adco begin neem

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- Venlafaxine XR Adco is aan u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet

1. Wat Venlafaxine XR Adco is en waarvoor dit gebruik word
2. Wat u moet weet voordat u Venlafaxine XR Adco neem
3. Hoe om Venlafaxine XR Adco te neem
4. Moontlike newe-effekte
5. Hoe om Venlafaxine XR Adco te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat Venlafaxine XR Adco is en waarvoor dit gebruik word

Venlafaxine XR Adco is 'n antidepressant wat behoort aan 'n groep medisyne genaamd serotonien- en norepinefrien-heropname inhibeerders (SNHI's). Hierdie groep medisyne word gebruik om depressie en ander toestande soos angsversteurings te behandel. Daar word vermoed dat mense wat depressief en/of angstig is, laer vlakke van serotonien en noradrenalien in die brein het. Dit word nie ten volle verstaan hoe antidepressante werk nie, maar dit kan help deur die vlakke van serotonien en noradrenalien in die brein te verhoog.

Venlafaxine XR Adco word gebruik om volwassenes met depressie te behandel, insluitend depressie wat verband hou met angs (gevoel van bekommernis of senuweeagtigheid). Venlafaxine XR Adco word ook gebruik om ernstige en aanhoudende angs (bekend as algemene angsversteuring), sosiale angsversteuring, ook bekend as sosiale fobie (vrees of

vermyding van sosiale situasies) te behandel.
Dit is belangrik om depressie of angsversteurings behoorlik te behandel, om u te help om beter te word. Indien dit nie behandel word nie, sal u toestand dalk nie opklaar nie en kan dit meer ernstig en moeiliker word om te behandel.
Venlafaxine XR Adco word gebruik om 'n terugslag van 'n episode van depressie te voorkom, of om herhaling te voorkom, en u dokter sal u van tyd tot tyd herevalueer.

2. Wat u moet weet voordat u Venlafaxine XR Adco neem

Moenie Venlafaxine XR Adco neem nie:

- indien u hipersensitief (allergies) is vir venlafaksien of vir enige van die ander bestanddele van Venlafaxine XR Adco (gelys in afdeling 6)
- indien u monoamienoksidase-inhibeerders (MAOIs) neem, 'n medisyne wat ook gebruik word om depressie of Parkinson se siekte te behandel, of dit in die afgelope 14 dae geneem het (u moet ook ten minste 7 dae wag nadat u Venlafaxine XR Adco gestaak het voordat u enige MAOI neem)
- indien u jonger as 18 jaar is
- indien u swanger is of u baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met Venlafaxine XR Adco:

- Indien u ander medisyne gebruik wat, wanneer dit saam met Venlafaxine XR Adco geneem word, die risiko kan verhoog om serotoniensindroom te ontwikkel (sien die afdeling "Ander medisyne en Venlafaxine XR Adco").
- Indien u oogprobleme het, soos sekere soorte gloukoom (verhoogde druk in die oog).
- Indien u 'n geskiedenis van hoë bloeddruk het.
- Indien u 'n geskiedenis van hartprobleme het.
- indien u 'n geskiedenis van miokardiale infarksie of onstabiele hartsiektes het.
- Indien u 'n geskiedenis van stuipaanvalle (konvulsies) het.
- Indien u 'n geskiedenis van lae natriumvlakke in u bloed het (hiponatremie).
- Indien u 'n neiging het om kneusplekke te ontwikkel of 'n neiging om maklik te bloei (geskiedenis van bloedingsversteurings), of indien u ander medisyne neem wat die risiko van bloeding kan verhoog, bv. warfarien (gebruik om bloedklonte te voorkom).
- Indien u swanger is, aangesien daar 'n verhoogde risiko van swaar vaginale bloeding kort na geboorte kan wees (sien 'Swangerskap' en 'Moenie Venlafaxine XR Adco neem nie').
- Indien u 'n geskiedenis van hoë cholesterol het.
- Indien u gewigsverlies medisyne neem.

- Indien u 'n geskiedenis het van manie of bipolêre versteuring (ooropgewonde of eufories voel), of indien iemand in u gesin dit gehad het.
- Indien u 'n geskiedenis van aggressiewe gedrag het.
- Indien u siftingstoetse vir fensiklidien en amfetamien moet ondergaan.

Gedagtes van selfdood en verergering van u depressie of angsversteuring
Indien u depressief is en/of angsversteurings het, kan u soms gedagtes hê om uself te beseer of dood te maak. Dit kan verhoog word wanneer u die eerste keer antidepressante begin neem, aangesien hierdie medisyne almal tyd neem om te werk, gewoonlik ongeveer twee weke, maar soms langer.

U is dalk meer geneig om so te dink:
- Indien u voorheen gedagtes gehad het om uself dood te maak of uself te beseer.
- Indien u 'n jong volwassene is. Inligting uit kliniese studies het 'n verhoogde risiko van selfdoodgedrag getoon by jong volwassenes (jonger as 25 jaar oud) met psigiatriese toestande wat met 'n antidepressant behandel is.

Indien u ter enige tyd gedagtes het om uself te beseer of dood te maak, kontak u dokter of gaan dadelik hospitaal toe.

Droë mond
Venlafaxine XR Adco kan 'n droë mond veroorsaak, dit kan die risiko van gaatjies in die tande verhoog en tandheelkundige higiëne is baie belangrik.

Diabetes
U bloedglukosevlakke kan verander word as gevolg van Venlafaxine XR Adco. Daarom moet die dosis van u diabetes-medisyne dalk aangepas word.

Seksuele probleme
Venlafaxine XR Adco (sogenaamde SNHIs) kan simptome van seksuele disfunksie veroorsaak (sien afdeling 4). In sommige gevalle het hierdie simptome voortgeduur nadat die behandeling gestaak is.

Raadpleeg u dokter voordat u Venlafaxine XR Adco neem, veral indien u:
- ‘n Geskiedenis van bloedingsversteurings het, of indien u swanger is (sien 'Swangerskap')

Kinders en adolessente
Moenie Venlafaxine XR Adco aan kinders en adolessente onder die ouderdom van 18 jaar gee

nie. Selfdoodverwante gedrag (selfdoodpoging en selfdoodgedagtes) en woede (hoofsaaklik aggressie, opposisiegedrag en woede) is meer gereeld onder kinders en adolessente waargeneem.

Ander medisyne en Venlafaxine XR Adco

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

U moet u dokter inlig indien u die volgende medisyne gebruik:

- Monoamienoksidase-inhibeerders (MAOI) wat gebruik word om depressie of Parkinson se siekte te behandel, moenie saam met Venlafaxine XR Adco geneem word nie. Lig u dokter in indien u hierdie medisyne binne die afgelope 14 dae geneem het (MAOIs: sien die afdeling “Wat u moet weet voordat u Venlafaxine XR Adco neem”).
- **Serotonien sindroom:**

'n Potensieel lewensgevaarlike toestand of Neuroleptiese Kwaadaardige Sindroom (NKS)-agtige reaksies (sien die afdeling ‘Moontlike newe-effekte’) kan voorkom tydens behandeling met Venlafaxine XR Adco, veral wanneer dit saam met ander medisyne geneem word. Voorbeelde van hierdie medisyne sluit in:

- Triptane (gebruik vir migraine)
- Ander medisyne om depressie te behandel, byvoorbeeld SNHIs, SSHIs, trisikliese antidepressante of medisyne wat litium bevat
- Medisyne wat amfetamiene bevat (wat gebruik word om aandagafleibaarheidsversteuring (ADHD), narkolepsie en vetsug te behandel)
- Medisyne wat sibutramien bevat (gebruik vir gewigsverlies)
- Medisyne wat tramadol, fentaniel, tapentadol, petidien of pentasosien bevat (word gebruik om erge pyn te behandel)
- Medisyne wat linesolied bevat, 'n antibiotikum (gebruik om infeksies te behandel)
- Medisyne wat moklobemied, 'n MAOI bevat (word gebruik om depressie te behandel)
- Medisyne wat dekstrometorfaan bevat (word gebruik om hoes te behandel)
- Medisyne wat metadoon bevat (word gebruik om opioïed dwelmverslawing of erge pyn te behandel)
- Medisyne wat metileenblou bevat (word gebruik om hoë vlakke van methemoglobien in die bloed te behandel)
- Produkte wat ‘St John's Wort’ bevat (ook genoem *Hypericum perforatum*, 'n natuurlike of kruiemiddel wat gebruik word om ligte depressie te behandel)
- Produkte wat triptofaan bevat (gebruik vir probleme soos slaap en depressie)
- Antipsigotika (word gebruik om 'n siekte te behandel met simptome soos om dinge te hoor, te sien of aan te voel wat nie daar is nie, verkeerde oortuigings, ongewone agterdogtigheid,

onduidelike redenasie en teruggetrokke houding)

Tekens en simptome van serotoniensindroom kan 'n kombinasie van die volgende insluit: rusteloosheid, hallusinasies, verlies aan koördinasie, vinnige hartklop, verhoogde liggaamstemperatuur, vinnige veranderinge in bloeddruk, ooraktiewe reflekse, diarree, koma, naarheid, braking.

In sy ernstigste vorm kan serotoniensindroom soos Neuroleptiese Kwaadaardige Sindroom (NKS) lyk. Tekens en simptome van NKS kan 'n kombinasie van koors, vinnige hartklop, sweet, erge spierstyfheid, verwarring, verhoogde spierensieme (bepaal deur 'n bloedtoets) insluit.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die bogenoemde simptome ervaar.

U moet u dokter inlig indien u medisyne neem wat u hartritme kan beïnvloed, soos:

- Middels teen disritmie soos kinidien, aminodaroon, sotalol of dofetilied (word gebruik om abnormale hartritme te behandel)
- Antipsigotika soos tioridasien (Sien ook ‘Serotoniensindroom’ hierbo)
- Antibiotika soos eritromisien of moksifloksasien (word gebruik om bakteriële infeksies te behandel)
- Antihistamiene (word gebruik om allergie te behandel)

Die volgende medisyne kan ook interaksie hê met Venlafaxine XR Adco en moet met versigtigheid gebruik word. Dit is veral belangrik om aan u dokter of apteker te noem indien u medisyne neem wat die volgende bevat:

- Ketokonasool ('n antifungus medisyne)
- Simetidien ('n teensuurmiddel), veral indien u bejaard is of lewerprobleme het
- Imipramien, bupropioon of fluoksetien (antidepressante)
- Ritonavir ('n antiretrovirale middel wat vir MIV/VIGS gebruik word)
- Haloperidol of risperidoon (vir die behandeling van psigiatriese toestande)
- Metoprolol ('n betablokker om hoë bloeddruk en hartprobleme te behandel)

Venlafaxine XR Adco met kos en alkohol

U moet geen alkohol neem wanneer u Venlafaxine XR Adco neem nie.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê,

raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u Venlafaxine XR Adco neem.

Swangerskap
Moenie Venlafaxine XR Adco neem indien u swanger is nie.
Indien u baba laat in die derde trimester aan Venlafaxine XR Adco blootgestel is, kan u baba simptome hê dat hy nie behoorlik voed na geboorte nie. Indien u baba hierdie simptome het wanneer dit gebore word en u is bekommerd, kontak u dokter en/of vroedvrou wat u sal kan adviseer.

Indien u Venlafaxine XR Adco naby die einde van u swangerskap neem, kan daar 'n verhoogde risiko van swaar vaginale bloeding kort na geboorte wees, veral indien u 'n geskiedenis van bloedingsversteurings het. U dokter of vroedvrou moet bewus wees dat u Venlafaxine XR Adco neem sodat hulle u kan adviseer.

Borsvoeding
Venlafaxine XR Adco word in borsmelk uitgeskei, daarom moet moeders wat hul babas borsvoed, nie Venlafaxine XR Adco neem nie.

Bestuur en gebruik van masjinerie
Venlafaxine XR Adco kan veroorsaak dat u duiselig en slaperig voel wat dus u oordeel, denke en motoriese vaardighede kan benadeel.

Dit is nie altyd moontlik om te voorspel in watter mate Venlafaxine XR Adco met u daaglikse aktiwiteite kan inmeng nie. Moenie betrokke raak by die bestuur van 'n voertuig of die gebruik van masjinerie voordat u bewus is van die mate waartoe Venlafaxine XR Adco u raak nie.

Venlafaxine XR 150 Adco bevat Allura Red AC (E129) en Sunset Yellow FCF (E110)
Allura Red AC (E129) en Sunset Yellow FCF (E110) kan allergiese reaksies veroorsaak.

Venlafaxine XR 225 Adco bevat die kleurstof Karmosien (E122)
Karmosien (E122) kan allergiese reaksies veroorsaak.

3. Hoe om Venlafaxine XR Adco te neem
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd Venlafaxine XR Adco presies soos u dokter u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Die algemene aanbevole aanvangsdosis vir Venlafaxine XR Adco vir die behandeling van depressie, algemene angsversteuring en sosiale angsversteuring is 75 mg per dag. Die dosis kan geleidelik deur u dokter verhoog word, en indien nodig, selfs tot en met 'n maksimum dosis van 375 mg daagliks vir depressie. Die maksimum dosis vir algemene angsversteuring, sosiale angsversteuring en paniekversteuring is 225 mg/dag.

Sluk die kapsule heel met vloeistof. Moenie kapsule verdeel, fyn maak, kou of in water sit nie.

Neem Venlafaxine XR Adco eenkeer per dag op dieselfde tyd, hetsy in die oggend of in die aand.

Venlafaxine XR Adco moet saam met kos geneem word.

Indien u lewer- of nierprobleme het, raadpleeg u dokter, aangesien u dosis Venlafaxine XR Adco dalk moet verander.
U dokter sal gereeld bepaal of u op langtermynterapie met Venlafaxine XR Adco moet wees.
U dokter sal u inlig hoe lank u behandeling met Venlafaxine XR Adco sal duur. Moenie die behandeling voortydig stop omdat u beter voel nie. Indien u die indruk het dat die effek van Venlafaxine XR Adco te sterk of te swak is, stel u dokter of apteker in kennis.

Indien u meer Venlafaxine XR Adco neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.
Die simptome van 'n moontlike oordosis kan 'n vinnige hartklop, veranderinge in waaksaamheid (wat wissel van slaperigheid tot koma), versteurde visie, stuipaanvalle of konvulsies, en braking insluit.

Indien u vergeet om Venlafaxine XR Adco te neem
Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Indien u Venlafaxine XR Adco staak
Moenie u behandeling staak of die dosis verminder sonder die advies van u dokter nie, selfs al voel u beter. Indien u dokter dink dat u nie meer Venlafaxine XR Adco nodig het nie, kan hy/sy u vra om u dosis stadig te verminder voordat u die behandeling heeltemal stop. Dit is bekend dat newe-effekte voorkom wanneer mense ophou om Venlafaxine XR Adco te gebruik, veral wanneer dit skielik gestaak word, of die dosis te vinnig verminder word. Sommige pasiënte kan

simptome ervaar soos moegheid, duiseligheid, lighoofdigheid, hoofpyn, slapeloosheid, nagmerries, droë mond, verlies aan eetlus, naarheid, diarree, senuweeagtigheid, agitasie, verwarring, gelui in die ore, tinteling of selde elektriese skok-sensasies, swakheid, sweet, stuipaanvalle of griepagtige simptome.

U dokter sal u adviseer oor hoe u Venlafaxine XR Adco behandeling geleidelik moet staak. Indien u enige van hierdie of ander simptome ervaar wat lastig is, vra u dokter vir verdere advies.

4. Moontlike newe-effekte

Venlafaxine XR Adco kan newe-effekte hê.
Nie alle newe-effekte wat vir Venlafaxine XR Adco aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of u enige ongewenste gevolge ervaar terwyl u Venlafaxine XR Adco neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg-verskaffer vir advies.

Indien enige van die volgende gebeur, staak Venlafaxine XR Adco en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- veluitslag of jeukerigheid,
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op Venlafaxine XR Adco gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- Hartprobleme, soos vinnige of onreëlmatige hartklop, verhoogde bloeddruk.
- Benoudheid op die bors, hygende asemhaling, probleme met sluk of asemhaling.
- Erge veluitslag, jeuk of galbulte (verhoogde kolle rooi of bleek vel wat dikwels jeuk).
- Tekens en simptome van serotoniensindroom wat rusteloosheid, hallusinasies, verlies aan koördinasie, vinnige hartklop, verhoogde liggaamstemperatuur, vinnige veranderinge in bloeddruk, ooraktiewe reflekse, diarree, koma, naarheid, braking kan insluit.

In sy mees ernstige vorm kan serotoniensindroom soos Neuroleptiese Kwaardaardige Sindroom (NKS) lyk. Tekens en simptome van NKS kan 'n kombinasie van koors, vinnige hartklop, sweet, erge spierstyfheid, verwarring, verhoogde spierensieme (bepaal deur 'n bloedtoets) insluit.

- Tekens van infeksie, soos hoë temperatuur, kouekoors, bewing, hoofpyn, sweet, griepagtige simptome. Dit kan die gevolg wees van 'n bloedafwyking wat lei tot 'n verhoogde risiko van infeksie.
- Erge veluitslag, wat kan lei tot ernstige blaasvorming en afskilfering van die vel.
- Onverklaarbare spierpyn, -teerheid of -swakheid. Dit kan 'n teken van rabdomiolise wees.
- Gedagtes om uself te beseer of dood te maak.

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

Gereelde newe-effekte:

- verminderde eetlus
- probleme met slaap
- abnormale drome, senuweeagtigheid
- verminderde libido, abnormale ejakulasie/orgasme (mans)
- duiseligheid, slaperigheid, rukkerigheid
- parestesie (abnormale sensasie, tipies tinteling of prikkeling)
- veranderde smaak
- versteurde visie, verwyde pupille, sigverlies, onvermoë van die oog om outomaties fokus van ver na naby voorwerpe te verander
- warm gloede
- gaap
- naarheid, droë mond, hardlywigheid, braking, maagpyn
- 'n abnormaal hoë vlak van spiertonus of -spanning, rugpyn
- onvermoë om te urineer; sukkel om te urineer
- impotensie
- moegheid, gebrek aan energie, pyn
- gewigstoename, gewigsverlies
- verhoogde cholesterol

Minder gereelde newe-effekte:

- ooraktiwiteit, jaende gedagtes en verminderde behoefte aan slaap (manie)
- voel ooropgewonde (hipomanie)
- hallusinasies
- derealisasie (gevoel dat 'n mens se omgewing nie werklik is nie), apatie (gebrek aan belangstelling)
- abnormale orgasme

- onwillekeurige spiere wat ruk of spring; stuipaanvalle
- duiselig voel (veral indien u te vinnig opstaan)
- sensitiwiteit vir sonlig; kneusplekke

Frekwensie onbekend:

- sensasie van in-die-rondte-draai en verlies aan balans
- bloedafwykings soos granulosiete in die bloed, tekort aan alle soorte bloedselle wat veroorsaak word deur beenmurgontwikkeling wat nie plaasvind nie, rooi selle, wit selle en bloedplaatjie-tekort (pansitopenie), bloedplaatjie-tekort in die bloed (trombositopenie) (sal deur 'n bloedtoets bepaal word)
- oormatige waterretensie (bekend as SIADH)
- abnormale borsmelkproduksie
- afname in bloednatriumvlakke
- verhoogde eetlus
- verwarring, voel geskei (of losgemaak) van uself
- agitasie
- kners van tande (veral tydens slaap)
- hoofpyn
- 'n gevoel van rusteloosheid of 'n onvermoë om stil te sit of te staan
- onwillekeurige bewegings van die spiere
- balansversteuring
- spierspasma en abnormale postuur
- nouhoek-gloukoom
- gelui in die ore
- lae bloeddruk
- inflammasie van die longe
- hoes, hygende asemhaling en kortasem wat gepaard kan gaan met 'n hoë temperatuur
- seer keel, loopneus, nies
- braking van bloed, swart teeragtige stoelgang (ontlasting) of bloed in stoelgang, wat tekens van bloeding in die spysverteringskanaal kan wees
- erge buik- of rugpyn, naar voel en braking wat kan dui op inflammasie van die pankreas
- diarree
- erge gewigsverlies (anoreksie)
- slegte spysvertering, winde opbreek, winde laat (flatus)
- verhoogde lewerfunksietoetse (bepaal deur 'n bloedtoets)
- jeukerigheid, geel vel of oë, donker urien of griepagtige simptome, wat simptome van

inflammasie van die lewer (hepatitis) is
- oormatige sweet (insluitend nagsweet)
- galbulte, haarverlies, swelling van die bene en arms
- bultende, uitslagagtige letsel wat rooi, pienk, pers of bruin is
- spierpyn
- verhoogde frekwensie in urinering
- onwillekeurige lekkasie van urien
- menstruele onreëlmatighede soos verhoogde bloeding of verhoogde onreëlmatige bloeding
- kouekoors
- onverwagte bloeding, bv. bloeiende tandvleis, bloed in die urien of in braaksel, of die voorkoms van onverwagte kneusplekke of lekkende bloedvate (spatare)
- langdurige bloeding - indien u uself sny of beseer, kan dit effens langer as gewoonlik neem voordat bloeding stop
- swaar vaginale bloeding kort na geboorte (post-partum bloeding)

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u enige newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die vorm "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 u help om meer inligting oor die veiligheid van Venlafaxine XR Adco te verskaf.

5. Hoe om Venlafaxine XR Adco te bêre

BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Bêre teen of benede 25 °C. Bêre in oorspronklike verpakking totdat dit benodig word vir gebruik.

Beskerm teen lig en vogtigheid. Hou HDPE-houers dig toe.

Neem alle ongebruikte medisyne terug na u apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat Venlafaxine XR Adco bevat

Venlafaxine XR 37,5 Adco: Die aktiewe bestanddeel is venlafaksienhidrochloried gelykstaande

aan 37,5 mg venlafaksien vrye basis.
Die ander bestanddele is:
Kapsule se inhoud (mini-tablette):
Kern: mikrokristallyne sellulose, kolloïdale silikondioksied, magnesiumstearaat, povidoon, talk.
Filmbedekking: kopovidoon, etielsellulose.
Kapsuledop: gelatien, ysteroksied swart (E172), ysteroksied rooi (E172), ysteroksied geel (E172), titaandioksied (E171), gesuiwerde water.
Kapsule gedrukte ink: butielalkohol, ontwaterde alkohol (E1510), isopropielalkohol, propileenglikol (E1520), skilferlak (E904), gekonsentreerde ammoniakoplossing (E527), ysteroksiedrooi (E172).

Venlafaxine XR 75 Adco: Die aktiewe bestanddeel is venlafaksienhidrochloried gelykstaande aan 75 mg venlafaksien vrye basis.
Die ander bestanddele is:
Kapsule se inhoud (mini-tablette):
Kern: mikrokristallyne sellulose, kolloïdale silikondioksied, magnesiumstearaat, povidoon, talk.
Filmbedekking: kopovidoon, etielsellulose.
Kapsuledop: gelatien, ysteroksied swart (E172), ysteroksiedrooi (E172), titaandioksied (E171), gesuiwerde water.
Kapsule gedrukte ink: butielalkohol, ontwaterde alkohol (E1510), isopropielalkohol, propileenglikol (E1520), skilferlak (E904), gekonsentreerde ammoniakoplossing (E527), ysteroksiedrooi (E172).

Venlafaxine XR 150 Adco: Die aktiewe bestanddeel is venlafaksienhidrochloried gelykstaande aan 150 mg venlafaksien vrye basis.
Die ander bestanddele is:
Kapsule se inhoud (mini-tablette):
Kern: mikrokristallyne sellulose, kolloïdale silikondioksied, magnesiumstearaat, povidoon, talk.
Filmbedekking: kopovidoon, etielsellulose.
Kapsuledop: gelatien, briljante blou FCF (E133), Allura Red AC (E129), Sunset Yellow FCF (E110), titaniumdioksied (E171), gesuiwerde water.
Kapsule gedrukte ink: butielalkohol, gedehidreerde alkohol (E1510), isopropielalkohol, propileenglikol (E1520), skilferlak (E904), natriumhidroksied, povidoon, titaandioksied (E171).

Venlafaxine XR 225 Adco: Die aktiewe bestanddeel is venlafaksienhidrochloried gelykstaande aan 225 mg venlafaksien vrye basis.
Die ander bestanddele is:

Kapsule se inhoud (mini-tablette):
Kern: mikrokristallyne sellulose, kolloïdale silikondioksied, magnesiumstearaat, povidoon, talk.
Filmbedekking: kopovidoon, etielsellulose.
Kapsuledop: Karmosien (E122), gelatien, titaandioksied (E171), gesuiwerde water.
Kapsule gedrukte ink: butielalkohol, ontwaterde alkohol (E1510), isopropielalkohol, propileenglikol (E1520), skilferlak (E904), gekonsentreerde ammoniakoplossing (E527), Indigo-karmyn (E132) lak.

Hoe Venlafaxine XR Adco lyk en die inhoud van die verpakking
Venlafaxine XR 37,5 Adco is 'n liggrys ondeursigtige/perske-kleurige ondeursigtige, grootte "3" harde gelatienkapsule met breë en smal radiale sirkels op die basis in rooi ink, en breë en smal radiale sirkels op die dop in rooi ink, gevul met wit tot naaswit, ronde, bikonvekse, filmbedekte mini-tablette.

Venlafaxine XR 75 Adco is 'n perske-kleurige ondeursigtige/perske-kleurige ondeursigtige grootte "1" harde gelatienkapsule met breë en smal radiale sirkels op die basis in rooi ink, en breë en smal radiale sirkels op die dop in rooi ink, gevul met wit tot naaswit, ronde, bikonvekse, filmbedekte mini-tablette.

Venlafaxine XR 150 Adco is 'n donker-oranje/donker-oranje ondeursigtige grootte "0" harde gelatienkapsule met breë en smal radiale sirkels op die basis in wit ink, en breë en smal radiale sirkels op die dop in wit ink, gevul met wit tot naaswit, ronde, bikonvekse, filmbedekte mini-tablette.

Venlafaxine XR 225 Adco is 'n pienk ondeursigtige/pienk ondeursigtige, grootte "00" harde gelatienkapsule met breë en smal radiale sirkels op die basis in blou ink, en breë en smal radiale sirkels op die dop in blou ink, gevul met mini-tablette.

Venlafaxine XR Adco verlengde-vrystelling kapsules is verpak in:
- Aluminium/aluminiumfoelie stulpstroke (slegs vir die 225 mg kapsules)
- Aluminiumfoelie en wit ondeursigtige PVC-Aclar-filmstulpstroke
- Aluminiumfoelie en wit ondeursigtige PVC-PVdC-filmstulpstroke
- Wit HDPE-houers met kinderbestande prop, en 'n absorberende katoenwatte (slegs vir die 37,5 mg, 75 mg en 150 mg kapsules)

Verpakkingsgroottes: 10 of 14 kapsules per stulpstrook in 'n verpakking van 10, 14, 28, 30 of 100 kapsules in 'n buitenste kartonboksie saam met professionele inligting en/of pasiënt

inligtingsbiljet. 30, 100, 500 of 1 000 kapsules per HDPE-houer.
Nie alle verpakkingsgroottes mag dalk bemark word nie.

Houer van Sertifikaat van Registrasie

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Hierdie biljet is mees onlangs hersien op

13 May 2025

Registrasienommers

Venlafaxine XR 37,5 Adco:	43/1.2/0577
Venlafaxine XR 75 Adco:	43/1.2/0578
Venlafaxine XR 150 Adco:	43/1.2/0579
Venlafaxine XR 225 Adco:	52/1.2/0438

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