

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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PATIENT INFORMATION LEAFLET

VOLOXIN (extended release tablet)

Desvenlafaxine

Read all of this leaflet carefully before you start taking VOLOXIN.

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

1. What VOLOXIN is and what it is used for

VOLOXIN is used to treat depression.

VOLOXIN belongs to a class of medicines known as SNRIs (serotonin-norepinephrine reuptake inhibitors).

2. What you need to know before you take VOLOXIN

Do not take VOLOXIN:

- if you are hypersensitive (allergic) to desvenlafaxine, venlafaxine or any of the ingredients of VOLOXIN.
- If you are taking a monoamine oxidase inhibitor (MAOI) used to treat mental diseases (e.g. rasagiline, selegiline) or to treat bacterial infections (e.g. linezolid). At least 14 days should elapse between stopping a MAOI and starting VOLOXIN.
- If you are less than 18 years of age.
- if you are pregnant or breastfeeding your baby.

Take special care with VOLOXIN:

- if you experience worsening of your depression, or if you have suicidal thoughts or behaviour. You should contact your doctor immediately.
- if you are bipolar or have mania.
- if you have glaucoma.
- if you have heart problems.
- if you have a high blood pressure.
- if you have been on VOLOXIN for a long time and stop suddenly.
- if you have high cholesterol or high triglycerides.
- if you have a history of a stroke.
- if you have kidney problems.
- if you have liver problems.

- if you have lung problems.
- if you have abnormal bleeding problems.
- if you have or had fits, seizures or convulsions.
- if you have low sodium levels in your blood.

Rare, but potentially life-threatening conditions called serotonin syndrome can happen when medicines such as VOLOXIN are taken with certain other medicines. Serotonin syndrome can cause serious changes in how your brain, muscles, heart and blood vessels, and digestive system work.

Taking other medicines with VOLOXIN:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

See Do not take VOLOXIN.

Tell your doctor if you are taking or using any of the following medicines:

- Monoamine oxidase inhibitors (MAOIs) including:
 - selegiline which is used to treat Parkinson's disease and depression.
 - linezolid which is an antibiotic.
 - intravenous methylene blue which is used for a condition occurs when the blood cannot deliver oxygen where it is needed in the body.
- Medicines that affect your central nervous system (CNS), which is responsible for processing and controlling most of our bodily functions, such as amphetamine which is used in the treatment of attention deficit hyperactivity disorder and obesity.
- Selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine), serotonin and noradrenaline reuptake inhibitors (SNRIs) (e.g. venlafaxine, desvenlafaxine), tricyclic

antidepressants (e.g. amitriptyline, desipramine), St. John's Wort: medicines used to treat depression.

- Triptans (e.g. sumatriptan): medicines used to treat migraine headaches.
- Amino acid supplements used to help control your mood and sleep known as tryptophan supplements
- Lithium: medicine used to treat mental illnesses.
- Sibutramine: medicine used for weight loss.
- Tramadol, pethidine: medicine used to treat pain.
- Warfarin, aspirin: medicines used to stop blood clots from forming.
- Non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. diclofenac, ibuprofen): medicines used to treat pain and inflammation.
- Laboratory tests for phencyclidine (PCP) and amphetamine as you may receive a false positive result.

Pregnancy, breastfeeding and fertility

You should not take VOLOXIN if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before VOLOXIN is administered to you.

Driving and using machines

Since adverse reactions such as dizziness, tiredness, disturbance in attention and blurred vision have been reported in patients receiving VOLOXIN, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that VOLOXIN does not adversely affect your ability to do so.

Important information about some of the ingredients of VOLOXIN

VOLOXIN is sugar free.

3. How to take VOLOXIN

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

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

The usual dose is for VOLOXIN is 50 mg once daily, with a maximum dose of 100 mg per day. The dose increase should occur gradually and at an interval of not less than 7 days.

Take VOLOXIN at about the same time each day.

Swallow VOLOXIN whole, with fluid. Do not crush, cut, chew, or dissolve VOLOXIN because the tablets are time-released.

Do not stop taking or change the dose of VOLOXIN without talking with your healthcare provider, even if you feel better.

Taking VOLOXIN with food and drink

VOLOXIN may be taken at any time of the day, with or without food. Avoid alcohol consumption while taking VOLOXIN.

If you have the impression that the effect of VOLOXIN is too strong or too weak, tell your doctor or pharmacist.

If you take more VOLOXIN than you should

In the event of over dosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of VOLOXIN

If you have missed a dose of VOLOXIN, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten dose. If you have forgotten to take several doses contact your doctor without delay.

If you stop taking VOLOXIN

If you suddenly stop taking VOLOXIN or if the dose is lowered, especially if you have been taking VOLOXIN for a long time, you may experience withdrawal symptoms such as nausea, dizziness, headache, irritability, agitation, anxiety, tiredness and emotional instability.

4. Possible side effects

VOLOXIN can have side effects.

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

If any of the following happens, stop taking VOLOXIN 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,

- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).

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

- Coma;
- seizures (convulsions);
- chest pain, neck or jaw pain, shoulder or arm pain, fast or irregular heartbeat, shortness of breath when you are physically active, and sweating;
- upper abdominal pain, abdominal pain that radiates to your back, abdominal pain that feels worse after eating, fever, rapid pulse, tenderness when touching the abdomen caused by an inflammation of the pancreas (acute pancreatitis).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Decreased appetite;
- inability to sleep (insomnia), sleepiness (somnolence), anxiety, nervousness, abnormal dreams, nervousness, decreased libido, inability to achieve an orgasm;
- dizziness, headache, tremor, disturbance in attention, distortion of the sense of taste, tingling or pricking ('pins and needles') (paraesthesia), spinning sensation (vertigo);
- blurred vision, dilation of the pupil (mydriasis);

- ringing in the ears (tinnitus);
- hot flushes;
- yawning;
- nausea, dry mouth, constipation, vomiting, diarrhoea, sweating;
- muscle stiffness;
- ejaculation delayed, ejaculation failure, erectile dysfunction;
- fatigue, chills, feeling jittery, abnormal physical weakness or lack of energy (asthenia), irritability;
- increased or decreased weight.

Less frequent side effects:

- Low sodium levels in your blood (symptoms of this may include headache, difficulty concentrating, memory changes, confusion, weakness and unsteadiness on your feet. In severe or more sudden cases, symptoms can include hallucinations, fainting, seizures and coma)(hyponatraemia);
- withdrawal symptoms;
- abnormal orgasm, feeling disconnected or detached from your body and thoughts, feeling like you are observing yourself from outside your body or like being in a dream (depersonalisation), an extreme increase in activity and talking (hypomania), seeing and hearing things that are not real (hallucinations), excessive teeth grinding or jaw clenching;
- involuntary muscle contractions that cause repetitive or twisting movements (dystonia)
- increased blood pressure, feeling lightheaded or dizzy after standing up due to low blood pressure (orthostatic hypotension), coldness in the hands and feet;
- nosebleeds;
- baldness or loss of hair, sensitivity of the skin to exposure to the sun;

- difficulty with urination, not being able to fully empty the bladder, protein in the urine;
- problems with ejaculation, sexual dysfunction;
- abnormal tests results indicating how the liver and kidneys are working.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via:

SAHPRA: <https://www.sahpra.org.za/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store VOLOXIN

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C.

Protect from moisture.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VOLOXIN contains

The active substance is desvenlafaxine.

Each extended release tablet of VOLOXIN 50 mg contains desvenlafaxine succinate equivalent to 50 mg desvenlafaxine.

Each extended release tablet of VOLOXIN 100 mg contains desvenlafaxine succinate equivalent to 100 mg desvenlafaxine.

The other ingredients are hypromellose, iron oxide (E172), macrogol, magnesium stearate, microcrystalline cellulose, povidone, talc and titanium dioxide (E171).

What VOLOXIN looks like and contents of the pack

VOLOXIN 50 mg

Light pink coloured, round, biconvex, film coated tablets, debossed with '50' on one side and plain on other side

VOLOXIN 100 mg

Dark brown to red coloured, round, biconvex, film coated tablets, debossed with '100' on one side and plain on other side

7, 14 or 28 tablets are packed in silver aluminium/aluminium foil blisters. Blister strips are packed in an outer cardboard carton.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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Healthcare Park

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