PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

VOXBRINT 5 film-coated tablets

VOXBRINT 10 film-coated tablets

VOXBRINT 20 film-coated tablets

Vortioxetine

Contains sugar alcohol:

VOXBRINT 5 contains 11,25 mg mannitol per tablet.

VOXBRINT 10 contains 22,5 mg mannitol per tablet.

VOXBRINT 20 contains 45,0 mg mannitol per tablet.

Read all of this leaflet carefully before you start taking VOXBRINT

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

1. What VOXBRINT is and what it is used for

VOXBRINT contains the active substance vortioxetine that belongs to a group of medicines called antidepressants.

VOXBRINT is used to treat major depressive episodes in adults and to reduce the risk of relapsing to these depressive episodes.

VOXBRINT reduces the symptoms of depressive episodes, such as sadness, feeling empty or hopeless, feelings of anger or frustration, losing interest in normal activities, difficulties sleeping or sleeping too much, feeling worthless and guilty, losing your appetite, feeling anxious or restless, difficulties in concentrating or making decisions and feeling slowed down.

2. What you need to know before you take VOXBRINT

Do not take VOXBRINT:

- If you are hypersensitive (allergic) to vortioxetine or any of the other ingredients of VOXBRINT listed in section 6 of this leaflet.
- If you are taking any other medicine for depression belonging to a class of medicines called monoamine oxidase inhibitors (MAOIs) including linezolid. Ask your doctor if you are uncertain.

Warnings and precautions:

Thoughts of harming yourself and worsening of your symptoms

Tell your doctor if you have or previously had thoughts of harming or killing yourself. If you are depressed, you may sometimes experience these thoughts. When starting treatment with VOXBRINT, you may experience an increase in the ideas of harming or killing yourself in the first few weeks, since VOXBRINT takes time to work. Your doctor may monitor you during this time.

You may be more likely to experience these thoughts if you have previously had feelings of harming or killing yourself, or if you are a young adult (under 25 years of age).

If you have thoughts of harming or killing yourself or experience a worsening of your depressive symptoms, tell your doctor or caregiver immediately or go to a hospital. You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. They may help to recognise when your symptoms worsen or when you experience changes in your behaviour.

Take special care with VOXBRINT:

- If you are taking medicines that has an effect on serotonin levels in your body, such as medicines used to treat migraine (ending in “triptan”), depression (monoamine oxidase inhibitors), psychosis and hallucinations. Taking these medicines together with VOXBRINT may increase the risk of developing a condition of excess serotonin in your body, called serotonin syndrome. Tell your doctor immediately if you develop symptoms, such as hallucinations, feeling agitated, a rapid heartbeat, high blood pressure, feeling hot, overactive reflexes, loss of coordination, nausea (feeling sick), vomiting (being sick) and diarrhoea.
- If you have had fits (seizures) or have epilepsy. Your doctor will treat you cautiously if you have a history of fits or epilepsy and will determine your treatment.
- If you have previously had mania or hypomania (sleeplessness, having delusions and being overactive).
- If you are taking medicine to prevent blood clots (anticoagulants) or medicine that may affect your body’s ability to form blood clots (such as medicine used to treat psychosis and schizophrenia, other antidepressants and medicine used to treat pain and inflammation).
- If you have a bleeding disorder.
- If you have low sodium level in the blood.
- If you suffer from glaucoma (an eye disorder).
- If you are 65 years of age or older.
- If you have a severe kidney or liver disease.
- If you become agitated or aggressive.

Children and adolescents:

Safety and efficacy in children and adolescents under the age of 18 years have not been established.

Other medicines and VOXBRINT:

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

Tell your doctor or pharmacist before you take VOXBRINT if you use:

- Any medicine called a monoamine oxidase inhibitor, including moclobemide (used to treat depression), selegiline and rasagiline (used to treat Parkinson's disease). If your doctor tells you to stop taking any of these medicines and prescribes you VOXBRINT, you need to wait 14 days after stopping the medicine before taking VOXBRINT. If your doctor tells you to stop taking VOXBRINT and start taking a monoamine oxidase inhibitor medicine, you also need to wait 14 days after stopping VOXBRINT before taking the new medicine.
- Linezolid (used to treat bacterial infection). Your doctor may monitor you if you are prescribed VOXBRINT with linezolid.
- Pethidine or tramadol (used to treat pain).
- Sumatriptan or any other medicine ending in "triptan" (used to treat migraine).
- Any other antidepressant medicines.
- St. John's wort (herbal medicine used to treat symptoms of mild depression or anxiety).
- Medicine used to treat psychotic disorders (such as phenothiazines, thioxanthenes and butyrophenones).
- Bupropion (used to treat depression or to stop smoking).
- Mefloquine (used to prevent and treat malaria).
- Quinidine (used to treat heart dysrhythmia).
- Rifampicin (antibiotic used to treat tuberculosis (TB)).

- Carbamazepine (used to treat seizures or nerve pain) or phenytoin (used to treat seizures).
- Anticoagulant- or antiplatelet medicine (used to prevent blood clots).
- Lithium (used as a mood stabiliser) or tryptophan (used as a mood stabiliser or to treat insomnia).

Tell your doctor or pharmacist before you take VOXBRINT:

- If you have previously been informed that your body metabolises certain medicines slowly (poor CYP2D6 metaboliser).
- If you are receiving treatment with electroconvulsive therapy.

Tell your doctor that you are taking VOXBRINT if you have to undergo urine drug screens, as your results may not be accurate.

VOXBRINT with food, drink and alcohol:

VOXBRINT can be taken with or without food. The use of alcohol is not advised while taking VOXBRINT.

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 health care provider for advice before taking VOXBRINT. You should not take VOXBRINT if you are pregnant or breastfeeding or if you are a woman of childbearing potential and not using any contraceptives.

Driving and using machines:

VOXBRINT may cause side effects, such as dizziness that may impair your ability to drive or operate machines. It is not always possible to predict to what extent VOXBRINT may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VOXBRINT affects them.

3. How to take VOXBRINT

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

Always take VOXBRINT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet of 10 mg VOXBRINT once a day.

Your doctor may lower your dose to 5 mg VOXBRINT once a day or increase your dose to 20 mg VOXBRINT once a day.

If you are elderly (65 years of age or older), your doctor may start your treatment with 5 mg VOXBRINT once a day.

Your doctor will tell you how long your treatment with VOXBRINT will last. If you have the impression that the effect of VOXBRINT is too strong or too weak, tell your doctor or pharmacist.

If you take more VOXBRINT than you should:

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Do this even if you do not feel any discomfort. Take any remaining tablets and the empty packaging with you.

Overdose signs could be dizziness, nausea, diarrhoea, stomach discomfort, itching of the whole body, sleepiness and flushing. Following intake of dosages several times higher than the prescribed dose, fits (seizures) and an infrequent condition called serotonin syndrome have been reported.

If you forget to take VOXBRINT:

If you forget to take a dose, take it as soon as you remember unless it is nearly time to take your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking VOXBRINT:

Do not stop taking VOXBRINT without consulting your doctor. Even if you feel better, your doctor will determine how long your treatment with VOXBRINT will last.

4. Possible side effects

VOXBRINT can have side effects.

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

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

- Swelling of your 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 VOXBRINT. 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:

- Serotonin syndrome (hallucinations, involuntary twitching, accelerated heartbeat, high blood pressure, fever, nausea and diarrhoea).
- Excessive or unexplained bleeding (including bruising, nose bleeding, gastrointestinal and vaginal bleeding).

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:

- Abnormal dreams.
- Feeling dizzy.
- Nausea (feeling sick) and vomiting (being sick).
- Diarrhoea or constipation.
- Excessive sweating (not related to heat or exercise).

Less frequent side effects:

- Blurry vision, eyes are sensitive to light.
- Nights sweats.
- Flushing of your skin.

Side effects of unknown frequency:

- Hyperprolactinaemia (infertility, irregular periods, milk discharge from nipples when not pregnant or breastfeeding, pain in breasts, vaginal dryness, and loss of sex drive).
- Low levels of sodium in your blood (feeling dizzy, weak, confused, sleepy or very tired, or feeling or being sick, fainting, fits or falls).
- Trouble sleeping, irritability, violent behaviour.
- Headache.
- Hives.

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. 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 VOXBRINT.

5. How to store VOXBRINT

- Store at or below 25 °C.
- Keep the blister strips in the outer container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VOXBRINT contains:

The active substance in VOXBRINT is vortioxetine.

VOXBRINT 5: Each film-coated tablet contains 5 mg vortioxetine (as vortioxetine hydrobromide).

VOXBRINT 10: Each film-coated tablet contains 10 mg vortioxetine (as vortioxetine hydrobromide).

VOXBRINT 20: Each film-coated tablet contains 20 mg vortioxetine (as vortioxetine hydrobromide).

The other ingredients are colloidal silicon dioxide, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, Opadry White (containing hypromellose, macrogol and titanium dioxide) and sodium starch glycolate.

What VOXBRINT looks like and contents of the pack:

VOXBRINT 5: White coloured, round shaped, biconvex, film-coated tablets debossed with "V" on one side and "5" on other side.

VOXBRINT 10: White coloured, almond shaped, biconvex, film-coated tablets debossed with "V" on one side and "10" on other side.

VOXBRINT 20: White coloured, almond shaped, biconvex, film-coated tablets debossed with "V" on one side and "20" on other side.

Clear transparent PVC/PVdC and aluminium foil blister strips with 10 or 14 film-coated tablets, packed in an outer cardboard container.

Pack size: 10, 14, 28 or 30 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration:

Dr. Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

Morningside

Sandton

2057

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