Patient information leaflet

SCHEDULING STATUS

S5

VORELLIX 5 film-coated tablets

VORELLIX 10 film-coated tablets

VORELLIX 15 film-coated tablets

VORELLIX 20 film-coated tablets

Vortioxetine hydrobromide

Contains sugar: 58,50 mg mannitol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

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

1. What VORELLIX is and what it is used for

VORELLIX (vortioxetine hydrobromide) belongs to a class of medicine known as antidepressants.

VORELLIX is indicated for the treatment of depression and to reduce the risk of it re-occurring.

2. What you need to know before you take VORELLIX

Do not take **VORELLIX** if you:

- Are hypersensitive (allergic) to vortioxetine or any of the other ingredients of **VORELLIX**
- Are taking medicines known as Monoamine Oxidase Inhibitors (MAOIs) such as tranylcypromine or moclobemide

Warnings and Precautions

Take special care with VORELLIX

The presence of other medical conditions may affect the use of **VORELLIX.** Tell your doctor or pharmacist if any of the following applies to you, as you may require special monitoring or a lower dose:

- If you are elderly.
- If you have kidney or liver problems.
- If you are depressed, have suicidal thoughts or if these suicidal thoughts are worsening.
- Have a history of seizures or epilepsy.
- If you are experiencing symptoms such as nausea, vomiting, diarrhoea, loss of consciousness, hallucinating, fast heart rate, feeling very cold, abnormal blood pressure that increases and decreases quite frequently, increase in reflexes and incoordination. These symptoms are collectively known as Serotonin Syndrome symptoms and can be life threatening. If this occurs, speak to your doctor immediately. Treatment with **VORELLIX** should be discontinued immediately and treatment must be started.
- If you are using other medication such as triptans (to treat migraines, headaches), MAOIs (antidepressant), antipsychotics (to treat delusions, hallucinations, paranoia or disordered thoughts in people suffering from conditions such as schizophrenia and bipolar disorder) and dopamine antagonists (used as an antipsychotic or to treat nausea and vomiting). This can lead to life threatening conditions known as Serotonin Syndrome (as discussed above) or Neuroleptic

Malignant Syndrome (altered mental status, muscle pain, autonomic dysfunction such as feeling dizzy, sudden change in blood pressure and exercise intolerance).

- A decrease in blood sodium levels (hyponatremia).
- Have a history of mental illness (mania/ hypomania).
- If you experience bleeding abnormalities and if you are using other medication to treat your condition such as anticoagulants (blood thinners), antipsychotics (to treat delusions, hallucinations, paranoia or disordered thoughts in people suffering from conditions such as schizophrenia and bipolar disorder), tricyclic antidepressants, NSAIDS (treats inflammation) or aspirin (to treat fever or mild to moderate pain).
- If you are taking bupropion (used to stop smoking or to treat depression) as it affects the breakdown of **VORELLIX.**
- If you experience aggression or agitation.
- If you have glaucoma (increased pressure in the eye) as **VORELLIX** may cause dilation of the pupils which may affect vision.

Children (and adolescents)

This medicine cannot be taken by children and adolescents under the age of 18.

Important information about some of the ingredients of VORELLIX

VORELLIX contains sugar in the form of 58,50 mg mannitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Tell your doctor or healthcare professional if you are allergic or intolerant to mannitol so that alternate therapy may be recommended. Mannitol may have a mild laxative effect.

Other medicines and VORELLIX

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

The following medicines or substances may increase or decrease blood levels and increase the risk of adverse events associated with **VORELLIX,** so please inform your doctor if you are taking the following:

- Monoamine oxidase inhibitors (MAOIs) used to treat depression such as tranylcypromine or moclobemide).
- Linezolid, an antibiotic to treat bacterial infections.
- Antidepressants used in combination with medicines that may increase the chances of developing Serotonin Syndrome such pethidine and tramadol used for pain relief or sumitriptans and other triptans such as rizatriptan or zolmitriptan which are used to treat migraines and headaches.
- St. John's Wort to treat mild depression, anxiety, stomach pain etc.
- Medication that may lower the seizure threshold such as antidepressants namely tricyclics, SSRI and SNRI (used to treat depression), neuroleptics such as phenothiazines, thioxanthenes and butyrophenones (used to treat psychosis such as schizophrenia or bipolar disorder), mefloquine (to treat malaria),

bupropion (to treat smoking, cravings and depression) and tramadol (for pain relief).

- Treatment that involves electrical stimulation of the brain to treat severe depression.
- Quinidine for irregular heartbeats.
- Fluoxetine for depression.
- Paroxetine to treat depression, anxiety, obsessive-compulsive disorder etc.
- Ketoconazole or fluconazole for the treatment of fungal infections.
- Rifampicin, an antibiotic used to treat tuberculosis and other bacterial infections.
- Carbamazepine or phenytoin used to treat and manage seizures.
- Aspirin used to reduce fever and mild to moderate pain.
- Warfarin or other blood thinning medicines.
- Alcohol.
- Diazepam used to treat anxiety, alcohol withdrawal, seizures, muscle pain or to provide a state of calm or sleep.
- Oral contraceptives to prevent pregnancy or to regulate your menstrual cycle.
- Lithium to treat bipolar disorder.
- Tryptophan used to treat depression.

Urine screening tests may produce false positive results while using **VORELLIX**. Consult your doctor to confirm the urine results with alternative testing methods.

VORELLIX with food and drink

The film-coated tablets can be taken with or without food.

Pregnancy, breastfeeding and fertility

Do not use **VORELLIX** if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **VORELLIX.**

Driving and using machinery

Caution should be taken when driving or operating machinery, especially when starting treatment or when changing the dose of **VORELLIX**.

3. How to take VORELLIX

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

Always take **VORELLIX** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 10 mg once daily with or without food. Your doctor may decide to adjust your dose accordingly. The maximum dose is 20 mg daily and the minimum dose is 5 mg daily. Treatment should not be less than a week and can continue for 6 months after the depressive symptoms resolve.

VORELLIX is not recommended for people younger than 18 years old.

Please speak to your doctor if you are elderly, have kidney or liver problems or if you are taking any other medication so that he/ she can reduce the dose accordingly.

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

If you have the impression that the effect of **VORELLIX** is too strong or too weak, tell your

doctor or pharmacist.

If you take more VORELLIX than you should

In the event of overdosage, consult your pharmacist or doctor. If neither is available, contact the nearest hospital or poison control center.

In the event of an overdosage, you may experience the following side effects:

- nausea, diarrhoea and stomach discomfort,
- dizziness,
- itchy skin,
- drowsiness,
- redness and a warm feeling on the skin.

If you forget to take VORELLIX

Do not take a double dose to make up for forgotten individual doses

If you stop taking VORELLIX

Stopping of **VORELLIX** does not require gradual reduction of the dose. However, do not stop taking **VORELLIX** unless you are told to stop by your doctor.

4. Possible Side Effects

VORELLIX can have side effects

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious reaction to **VORELLIX**. 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 symptoms such as fever, increased reflexes, sweating, dilated pupils of the eye, diarrhoea, unintentional muscle movements (tremor) and/ or anxiety.

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,

- abnormal dreams,
- dizziness,
- nausea, diarrhoea, constipation and vomiting,
- itchy skin.

Less frequent:

- unconsciously grinding of the teeth,
- redness of the skin (flushing),
- night sweats,
- Dilated pupils of the eyes that may affect vision

The following side effects have been reported with unknown frequency:

- low sodium levels in the blood,
- Difficulty falling asleep
- Aggression, agitation
- Skin bruising or bleeding from the mouth, nose or stomach

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 to

SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8N or drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of **VORELLIX**.

5. How to store VORELLIX

- Store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN

6. Contents of the pack and other information

What VORELLIX contains:

VORELLIX 5: Each film - coated tablet contains vortioxetine hydrobromide equivalent to 5 mg vortioxetine.

VORELLIX 10: Each film - coated tablet contains vortioxetine hydrobromide equivalent to 10 mg vortioxetine.

VORELLIX 15: Each film - coated tablet contains vortioxetine hydrobromide equivalent to 15 mg vortioxetine.

VORELLIX 20: Each film - coated tablet contains vortioxetine hydrobromide equivalent to 20 mg vortioxetine.

The other ingredients are:

Tablet core: Amino methacrylate copolymer, colloidal silicon dioxide, mannitol, magnesium aluminometasilicate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

Tablet coating: Hypromellose, iron oxide red (5, 15 and 20 mg tablets), iron oxide yellow (10 and 15 mg tablets), macrogol, titanium dioxide.

Contains sugar: 58,50 mg mannitol

What VORELLIX looks like and contents of the pack:

VORELLIX 5: Pink coloured, almond shaped, biconvex, film-coated tablet debossed with “C5” on one side and “328” on the other side.

VORELLIX 10: Yellow coloured, almond shaped, biconvex, film-coated tablet debossed with “C10” on one side and “329” on the other side.

VORELLIX 15: Orange coloured, almond shaped, biconvex, film-coated tablet debossed with “C15” on one side and “543” on the other side.

VORELLIX 20: Reddish brown coloured, almond shaped, biconvex, film-coated tablet debossed with “C20” on one side and “331” on the other side.

VORELLIX 5, 10, 15, 20 is presented in a 50 cc HDPE container with 33 mm child resistant closure (blue) and silica gel bag 2,0 g containing 30 or 90 tablets per carton, or a 200 cc HDPE container with 38 mm white screw cap and silica gel bag 5,0 g containing 500 tablets per carton.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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