PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

VORTIOXETINE 5 ZYDUS film-coated tablet

Contains 5,6 mg mannitol (sugar alcohol) per film-coated tablet

VORTIOXETINE 10 ZYDUS film-coated tablet

Contains 5,8 mg mannitol (sugar alcohol) per film-coated tablet

VORTIOXETINE 20 ZYDUS film-coated tablet

Contains 11,7 mg mannitol (sugar alcohol) per film-coated tablet

Vortioxetine.

Read all of this leaflet carefully before you start taking VORTIOXETINE ZYDUS

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healtchare provider.
- VORTIOXETINE ZYDUS 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 VORTIOXETINE ZYDUS is and what it is used for

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

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

VORTIOXETINE ZYDUS 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 VORTIOXETINE ZYDUS

Do not take VORTIOXETINE ZYDUS:

- If you are hypersensitive (allergic) to vortioxetine or any of the other ingredients of VORTIOXETINE ZYDUS 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). 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 VORTIOXETINE ZYDUS, you may experience an increase in the ideas of harming or killing yourself in the first few weeks, since VORTIOXETINE ZYDUS 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 sympoms worsen or when you experience changes in your behaviour.

Take special care with VORTIOXETINE ZYDUS:

- 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 VORTIOXETINE ZYDUS 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 experience feelings of aggression, agitation, anger or irritability. If this occurs, you should talk to your doctor.
- 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 have or previously have had increased pressure in the eye or glaucoma. If your eyes become painful and you develop blurred vision during treatment, contact your doctor.
- If you are 65 years of age or older.
- If you have a severe kidney disease.
- If you have a severe liver disease or a liver disease called cirrhosis.

Children and adolescents

VORTIOXETINE ZYDUS should not be taken by children and adolescents under 18 years of age.

Other medicines and VORTIOXETINE ZYDUS

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 VORTIOXETINE ZYDUS if you use:

- Any medicine called a monoamine oxidase inhibitor, including moclobemide (used to treat depression). If your doctor tells to stop taking any of these medicines and prescribes you VORTIOXETINE ZYDUS, you need to wait 14 days after stopping the medicine before taking VORTIOXETINE ZYDUS. If your doctor tells you to stop taking VORTIOXETINE ZYDUS and start taking a monoamine oxidase inhibitor medicine, you also need to wait 14 days after stopping VORTIOXETINE ZYDUS before taking the new medicine.
- Linezolid (used to treat bacterial infection). Your doctor may monitor you if you are prescribed VORTIOXETINE ZYDUS 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 VORTIOXETINE ZYDUS:

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

VORTIOXETINE ZYDUS with food, drink and alcohol

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

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 VORTIOXETINE ZYDUS. You should not take VORTIOXETINE ZYDUS if you are pregnant or breastfeeding.

Driving and using machines

VORTIOXETINE ZYDUS may cause side effects, such as dizziness that may impair your ability to drive or operate machines. Do not drive or operate machines if you are affected by VORTIOXETINE ZYDUS.

3. How to take VORTIOXETINE ZYDUS

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

Always take VORTIOXETINE ZYDUS 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 VORTIOXETINE ZYDUS once a day.

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

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

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

If you take more VORTIOXETINE ZYDUS 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.

If you forget to take VORTIOXETINE ZYDUS

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 VORTIOXETINE ZYDUS

Do not stop taking VORTIOXETINE ZYDUS without consulting your doctor. Even if you feel

better, your doctor will determine how long your treatment with VORTIOXETINE ZYDUS will last.

4. Possible side effects

VORTIOXETINE ZYDUS can have side effects.

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

If any of the following happens, stop taking VORTIOXETINE ZYDUS 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 VORTIOXETINE ZYDUS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea, diarrhoea, constipation, vomiting
- dizziness
- abnormal dreams
- decreased appetite.

Less frequent side effects:

- flushing
- night sweats
- enlarged pupils (mydriasis), which can increase the risk of glaucoma (see section 2)

- excessive teeth grinding or jaw cletching (bruxism).

Frequency unknown:

- low levels of sodium in the blood (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)
- serotonin syndrome (see section 2)
- excessive or unexplained bleeding (including bruising, nose bleeding, gastrointestinal and vaginal bleeding)
- sleep disorders (insomnia)
- agitation and aggression. If you experience these side effects, contact your doctor (see section 2).

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 **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 VORTIOXETINE ZYDUS.

5. How to store VORTIOXETINE ZYDUS

- Store at or below 25 °C. Protect from light.
- Keep bottle tightly closed 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 VORTIOXETINE ZYDUS contains

The active substance in VORTIOXETINE ZYDUS is vortioxetine.

VORTIOXETINE 5 ZYDUS: Each film-coated tablet contains 5 mg vortioxetine.

VORTIOXETINE 10 ZYDUS: Each film-coated tablet contains 10 mg vortioxetine.

VORTIOXETINE 20 ZYDUS: Each film-coated tablet contains 20 mg vortioxetine.

The other ingredients are crospovidone, magnesium stearate, mannitol, microcrystalline cellulose, silicon dioxide.

VORTIOXETINE 5 ZYDUS: Opadry Pink containing: hypromellose (E464), iron oxide red (E172), iron oxide yellow (E172), macrogol (E1521) and titanium dioxide (E171).

VORTIOXETINE 10 ZYDUS: Opadry Yellow containing: D&C Yellow Nr. 10 Aluminium Lake, hypromellose (E464), iron oxide yellow (E172), macrogol (E1521), titanium dioxide (E171).

VORTIOXETINE 20 ZYDUS: Opadry Orange containing: D&C Yellow Nr. 10 Aluminium Lake, FD&C Red Nr. 40/Allura Red AC Aluminium Lake, hypromellose (E464), iron oxide red (E172), macrogol (E1521), titanium dioxide (E171).

What VORTIOXETINE ZYDUS looks like and contents of the pack

VORTIOXETINE 5 ZYDUS: Peach to pink coloured, oval, film-coated tablet, debossed with “13” on one side and “19” on the other side.

VORTIOXETINE 10 ZYDUS: Yellow coloured, oval, film-coated tablet, debossed with “1320” on one side and plain on the other side.

VORTIOXETINE 20 ZYDUS: Orange coloured, oval film-coated tablet, debossed with “1322” on one side and plain on the other side.

White, high-density polyethylene (HDPE), round bottle, closed with a white child resistant polypropylene (PP) cap, having ribs on the sides, and opening / closing instructions embossed on

top and a continuous threaded inner cap.

Pack size	HDPE bottle	PP cap
VORTIOXETINE 5 ZYDUS		
30 tablets	60 mL	33 mm
90 tablets	60 mL	33 mm
500 tablets	75 mL	38 mm
VORTIOXETINE 10 ZYDUS		
30 tablets	60 mL	33 mm
90 tablets	60 mL	33 mm
500 tablets	100 mL	38 mm
VORTIOXETINE 20 ZYDUS		
30 tablets	60 mL	33 mm
90 tablets	60 mL	33 mm
500 tablets	200 mL	38 mm

Holder of certificate of registration

Zydus Healthcare S.A. (Pty) Ltd

Southdowns Office Park,

Building B, Ground Floor

22 Karee Street

Centurion, 0157

012 748 6400

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VORTIOXETINE 10 ZYDUS: 55/1.2/0795.792

VORTIOXETINE 20 ZYDUS: 55/1.2/0796.793