## 1.3.2 PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

**S5**

**VORTIOXETINE 5 mg ASPEN film-coated tablets**

**Vortioxetine hydrobromide**

**Contains sugar: Mannitol 11,250 mg**

**VORTIOXETINE 10 mg ASPEN film-coated tablets**

**Vortioxetine hydrobromide**

**Contains sugar: Mannitol 22,500 mg**

**VORTIOXETINE 20 mg ASPEN film-coated tablets**

**Vortioxetine hydrobromide**

**Contains sugar: Mannitol 45,00 mg**

**Read all of this leaflet carefully before you start taking VORTIOXETINE ASPEN**

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

2. What you need to know before you take VORTIOXETINE ASPEN
3. How to take VORTIOXETINE ASPEN
4. Possible side effects
5. How to store VORTIOXETINE ASPEN
6. Contents of the pack and other information

## 1. What VORTIOXETINE ASPEN is and what it is used for

VORTIOXETINE ASPEN contains the active substance vortioxetine. It belongs to a group of medicines called antidepressants. VORTIOXETINE ASPEN is used to treat major depressive episodes in adults. VORTIOXETINE ASPEN has been shown to reduce the broad range of depressive symptoms, including sadness, inner tension (feeling anxious), sleep disturbances (reduced sleep), reduced appetite, difficulty in concentrating, feelings of worthlessness, loss of interest in favourite activities, feeling of being slowed down.

## 2. What you need to know before you take VORTIOXETINE ASPEN

**Do not take VORTIOXETINE ASPEN:**

- if you are hypersensitive (allergic) to vortioxetine or any of the other ingredients of VORTIOXETINE ASPEN (listed in section 6).
- if you are taking other medicines for depression known as non-selective monoamine oxidase inhibitors (e.g. isocarboxazid, phenelzine) or selective MAO-A inhibitors (e.g. selegiline). Ask your doctor if you are uncertain.

**Warnings and precautions**

Take special care with VORTIOXETINE ASPEN:

- If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting 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 or harming yourself.

  - are a young adult.

  Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years 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.

  You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.
- If you have had fits (seizures). Your doctor will treat you cautiously if you have a history of fits or have unstable fit disorders/epilepsy. Fits are a potential risk with medicines used to treat depression. Treatment should be discontinued in any patient who develops fits or where there is an increase in the frequency of fits.
- If you are taking medicines with a so-called serotonergic effect, such as:

  - tramadol (a strong pain killer).

  - sumatriptan and similar medicines with active substance names ending in “triptans” (used to treat migraine).

  Taking these medicines together with VORTIOXETINE ASPEN may increase the risk of serotonin syndrome (see Undesirable effects).
- If you have had mania.
- If you have a tendency to bleed or bruise easily.

- VORTIOXETINE ASPEN may cause bleeding after birth. Tell your doctor if you are pregnant and you are taking VORTIOXETINE ASPEN (see section titled Pregnancy, breastfeeding and fertility).
- If you have low sodium level in the blood.
- If you have liver problems.
- If you have kidney problems.

**Children**

VORTIOXETINE ASPEN is not recommended in children and adolescents under 18 years due to lack of information for this age group.

**Other medicines and VORTIOXETINE ASPEN**

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

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

- Phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine (medicines to treat depression called non-selective monoamine oxidase inhibitors) you must not take any of these medicines together with VORTIOXETINE ASPEN. If you have taken any of these medicines, you will need to wait 14 days before you start taking VORTIOXETINE ASPEN. After stopping VORTIOXETINE ASPEN, you must allow 14 days before taking any of these medicines.
- Moclobemide (a medicine to treat depression).
- Bupropion (a medicine used to treat depression of to help to stop smoking).
- Anti-depressants such as amitriptyline, fluoxetine, citalopram, venlafaxine. As these medicines may increase your risk to have a seizure.
- Selegiline and rasagiline (medicines to treat Parkinson's disease).

- Linezolid (a medicine to treat bacterial infections).
- St John's wort (*hypericum perforatum*) (a medicine to treat depression).
- Sumatriptan and similar medicines with active substance names ending in "triptans".
- Tramadol or pethidine (painkillers).
- Mefloquine (a medicine to prevent and treat malaria).
- Quinidine (a medicine to treat heart rhythm disorders).
- Rifampicin, used to treat tuberculosis (TB).
- Warfarin, used to prevent the clotting of your blood.
- Lithium, used to treat psychiatric conditions.

**VORTIOXETINE ASPEN with alcohol**

Combining VORTIOXETINE ASPEN with alcohol is not advisable. VORTIOXETINE ASPEN can be taken without regard to meals.

**Pregnancy, breastfeeding and fertility**

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

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 this medicine.

**Driving and using machines**

VORTIOXETINE ASPEN has no or negligible influence on the ability to drive and use machines. However, as adverse reactions such as dizziness have been reported, you

should exercise caution when driving or operating hazardous machinery, especially when starting treatment with VORTIOXETINE ASPEN or when changing the dose.

## 3. How to take VORTIOXETINE ASPEN

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

Always take VORTIOXETINE ASPEN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of VORTIOXETINE ASPEN is 10 mg once daily.

Your doctor will determine the correct dose for you depending on your condition.

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

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

**If you take more VORTIOXETINE ASPEN than you should**

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

If you take more VORTIOXETINE ASPEN than you should, you may experience symptoms like nausea, dizziness or light headedness when you stand up from sitting or lying down, diarrhoea, stomach discomfort, itchy skin, sleepiness and flushing.

**If you forget to take VORTIOXETINE ASPEN**

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

## 4. Possible side effects

VORTIOXETINE ASPEN can have side effects.

Not all side effects reported for VORTIOXETINE ASPEN are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking VORTIOXETINE ASPEN, please consult your healthcare provider for advice.

If any of the following happens, stop taking VORTIOXETINE ASPEN 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 VORTIOXETINE ASPEN. 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:

- Hallucinations, involuntary twitching, accelerated heartbeat, high blood pressure, fever, nausea and diarrhoea (serotonin syndrome).
- Bleeding, including bruising, bleeding from the nose, digestive system, vagina.
- Bleeding after giving birth to a baby (postpartum haemorrhage) (see section titled Pregnancy, breastfeeding and fertility).

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, vomiting,
- generalised pruritis.

*Less frequent side effects:*

- Teeth grinding,
- night sweats,
- abnormal dreams.

*Side effects with an unknown frequency:*

- Rash,
- low sodium blood levels.

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. You can also report side effects to:

**SAHPRA:** https://www.sahpra.org.za/health-products-vigilance/

**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 VORTIOXETINE ASPEN.

## 5. How to store VORTIOXETINE ASPEN

Store all medicines out of reach of children.

Store at or below 25 °C.

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 VORTIOXETINE ASPEN contains**

The active substance is 5 mg, 10 mg or 20 mg of vortioxetine.

The other ingredients are colloidal silicone dioxide, hydroxypropyl cellulose, hypromellose, macrogol, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, titanium dioxide

VORTIOXETINE 5 mg ASPEN: Contains sugar: Mannitol 11,250 mg

VORTIOXETINE 10 mg ASPEN: Contains sugar: Mannitol 22,500 mg

VORTIOXETINE 20 mg ASPEN: Contains sugar: Mannitol 45,00 mg

**What VORTIOXETINE ASPEN looks like and contents of the pack**

VORTIOXETINE 5 mg ASPEN:

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

VORTIOXETINE 10 mg ASPEN:

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

VORTIOXETINE 20 mg ASPEN:

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

10 tablets are sealed with PVC/PVdC base foil on one side and aluminium lid foil on the other side in the form of Alu-PVC/PVdC blisters and such 1 or 3 blister packs are further packed in a printed carton along with instructions for use. Pack-sizes of 10 or 30 film-coated tablets.

14 tablets are sealed with PVC/PVdC base foil on one side and aluminium lid foil on the other side in the form of Alu-PVC/PVdC blisters and such 1 or 2 blister packs are further packed in a printed carton along with instructions for use.
Pack-sizes of 14 or 28 film-coated tablets.

Not all packs or pack sizes may be marketed.

**Holder of Certificate of Registration**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

**Hotline:** 0800 122 912

**This leaflet was last revised in**

22 November 2022

**Registration number**

VORTIOXETINE 5 mg ASPEN: 54/1.2/0702

VORTIOXETINE 10 mg ASPEN: 54/1.2/0703

VORTIOXETINE 20 mg ASPEN: 54/1.2/0704

**Access to the corresponding Professional Information**

**SAHPRA Repository of Professional Information and Patient Information Leaflets:**

https://www.sahpra.org.za/pi-pil-repository/

**Aspen Pharmacare:**

**E-mail:** Medinfo@aspenpharma.com

**Tel:** 0800 118 088

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