

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

VORTIOXETINE 5 mg DYNA film coated tablets

VORTIOXETINE 10 mg DYNA film coated tablets

VORTIOXETINE 20 mg DYNA film coated tablets

Vortioxetine hydrobromide equivalent to vortioxetine

Each 5 mg VORTIOXETINE DYNA tablet contains sugar (mannitol 11,250 mg/tablet).

Each 10 mg VORTIOXETINE DYNA tablet contains sugar (mannitol 22,500 mg/tablet).

Each 20 mg VORTIOXETINE DYNA tablet contains sugar (mannitol 45,000 mg/tablet).

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

- 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 DYNA 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 DYNA is and what it is used for
2. What you need to know before you take VORTIOXETINE DYNA
3. How to take VORTIOXETINE DYNA
4. Possible side effects

APPROVED PATIENT INFORMATION LEAFLET

5. How to store VORTIOXETINE DYNA
6. Contents of the pack and other information

1. What VORTIOXETINE DYNA is and what it is used for

VORTIOXETINE DYNA belongs to a group of medicines called antidepressants and 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.

VORTIOXETINE DYNA is used to treat major depressive episodes in adults.

2. What you need to know before you take VORTIOXETINE DYNA

Do not take VORTIOXETINE DYNA:

- if you are hypersensitive (allergic) to vortioxetine, or to any of the ingredients of VORTIOXETINE DYNA (see section 6)
- if you are taking other medicines used to treat depression, known as monoamine oxidase inhibitors (MAOIs) or selective MAO-A inhibitors.

Warnings and precautions

Take special care with VORTIOXETINE DYNA:

- if you are depressed, you can sometimes have thoughts of harming or killing yourself. These feelings may be increased when first starting antidepressants such as VORTIOXETINE DYNA, since these medicines all take time to work, usually about two weeks but sometimes longer.

APPROVED PATIENT INFORMATION LEAFLET

You may be more likely to think like this:

- o if you have previously had thoughts about killing or harming yourself.
 - o if you are a young adult as information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant.
 - o 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, 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 painkiller), sumatriptan and similar medicines with active substance names ending in “triptans” (used to treat migraine). Taking these medicines together with VORTIOXETINE DYNA may increase the risk of serotonin syndrome. This syndrome may be associated with hallucinations, involuntary twitching, accelerated heartbeat, high blood pressure, fever, nausea, vomiting and diarrhoea.
- if blood tests indicate that you have low sodium level
- if you have had, or experience mania. This is characterized by profuse and rapidly changing ideas, exaggerated happiness and excessive physical activity. In such cases, it is important to contact your doctor who probably will change your medicine.

APPROVED PATIENT INFORMATION LEAFLET

- if you tend to bruise or bleed easily, including gastrointestinal and menstrual bleeding.
- if you are taking bupropion or fluoxetine (to treat major depressive disorder), quinidine (treatment for irregular heartbeat), paroxetine (treatment for depression, anxiety)
- if you are 65 years of age or older
- if you have kidney disease or liver disease.

Paediatric population

VORTIOXETINE DYNA is not recommended for the treatment of depression in patients aged less than 18 years since the safety and efficacy of VORTIOXETINE DYNA have not been established in this age group

Other medicines and VORTIOXETINE DYNA

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

Take special care if you take:

- 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 DYNA. If you have taken any of these medicines, you will need to wait 14 days before you start taking VORTIOXETINE DYNA. After stopping VORTIOXETINE DYNA you must allow 14 days before taking any of these medicines.
- moclobemide (a medicine to treat depression) (see section 2 Do not take VORTIOXETINE DYNA)
- linezolid (a medicine to treat bacterial infections)

APPROVED PATIENT INFORMATION LEAFLET

- selegiline, rasagiline (medicines to treat Parkinson's disease)
- tramadol, sumatriptan and similar medicines with active substance names ending in "triptans" (to treat pain)
- St John's wort (*hypericum perforatum*) (a herbal remedy for depression)
- fluoxetine (to treat major depressive disorder), paroxetine and other medicines to treat depression called SSRI/SNRIs, tricyclics, medicines used to manage psychosis in schizophrenia (i.e. phenothiazines like fluphenazine; thioxanthenes like flunitenzol; and butyrophenones like haloperidol), bupropion (a medicine to treat depression also used to wean from smoking)
- mefloquine (used to treat malaria)
- quinidine (irregular heartbeat)
- medicine called poor CYP2D6 metabolisers like itraconazole (used to treat fungal infection), voriconazole (used to treat fungal infection), clarithromycin (antibiotic used to treat infections), telithromycin (used to treat infection of the lungs), nefazodone (used to treat depression), conivaptan (used to treat low blood sodium levels), fluconazole (used to treat fungal and yeast infections) and amiodarone (used to treat irregular heartbeat) as your dose of VORTIOXETINE DYNA may be lowered.
- rifampicin (a medicine to treat tuberculosis and other infections) as your dose of VORTIOXETINE DYNA may be adjusted
- carbamazepine, phenytoin (medicines to treat epilepsy or other illness) as your dose of VORTIOXETINE DYNA may be adjusted
- warfarin, dipyridamole, phenprocoumon, low-dose acetylsalicylic acid (blood thinning medicines)

APPROVED PATIENT INFORMATION LEAFLET

- lithium or tryptophan (medicine to treat depression and mental disorders) as the effect of VORTIOXETINE DYNA may be enhanced

VORTIOXETINE DYNA with food and drink

VORTIOXETINE DYNA can be taken with or without food. Drinking alcohol with this medicine is not advisable.

Pregnancy, breastfeeding and fertility

Pregnancy

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using VORTIOXETINE DYNA.

VORTIOXETINE DYNA should not be used during pregnancy.

Breastfeeding

It is expected that the ingredients of VORTIOXETINE DYNA will pass into breast milk.

VORTIOXETINE DYNA is not to be used during breast-feeding. Your doctor will make a decision on whether you should stop breast-feeding or stop using VORTIOXETINE DYNA taking into account the benefit of breast-feeding for your child, and the benefit of therapy for you.

Driving and using machines:

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

APPROVED PATIENT INFORMATION LEAFLET

advised during such activities when beginning VORTIOXETINE DYNA treatment or changing the dose.

It is not always possible to predict to what extent VORTIOXETINE DYNA may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which VORTIOXETINE DYNA affects you.

Excipients with a known effect

VORTIOXETINE DYNA contains mannitol which may have a mild laxative effect.

3. How to take VORTIOXETINE DYNA

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

Adults:

The recommended dose of VORTIOXETINE DYNA is 10 mg taken as one daily dose in adults less than 65 years of age. The dose may be increased by your doctor to a maximum of 20 mg vortioxetine per day or lowered to a minimum of 5 mg per day depending on your response to treatment.

For elderly people 65 years of age or older, the starting dose is 5 mg vortioxetine taken once daily.

Children:

APPROVED PATIENT INFORMATION LEAFLET

VORTIOXETINE DYNA is not recommended for use in children and adolescents (less than 18 years old).

Your doctor will tell you how long your treatment with VORTIOXETINE DYNA will last. Do not stop treatment without talking to your doctor.

If you have the impression that the effect of VORTIOXETINE DYNA is too strong or too weak, speak to your doctor or pharmacist.

If you take more VORTIOXETINE DYNA than you should:

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

Symptoms of overdose may include:

- dizziness, nausea, diarrhoea, stomach discomfort, itching of the whole body, sleepiness and flushing.

If you forget to take VORTIOXETINE DYNA:

If you forget to take VORTIOXETINE DYNA, take as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking VORTIOXETINE DYNA

Do not stop taking VORTIOXETINE DYNA without talking with your doctor or other healthcare professional.

APPROVED PATIENT INFORMATION LEAFLET

4. Possible side effects

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

If any of the following happens, stop using VORTIOXETINE DYNA 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

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

- rapid heart rate and high blood pressure, dilated pupils, loss of muscle coordination or twitching muscles, muscle rigidity, heavy sweating, agitation or restlessness, confusion (symptoms of a condition called serotonin syndrome)

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

Tell your doctor if you notice any of the following:

APPROVED PATIENT INFORMATION LEAFLET

Frequent side effects:

- runny or stuffy nose, sneezing, coughing, sore throat, watery or itchy eyes, flu
- decreased appetite
- insomnia, abnormal dreams (nightmares)
- headache, dizziness, sleepiness, slurred speech
- nausea, diarrhoea, dry mouth, constipation, vomiting, flatulence, abdominal pain, bloated feeling
- excessive sweating, severe itching of the skin with bumps, spots or blisters (pruritis)
- back pain, swollen or painful joints
- fatigue (extreme tiredness)
- accidental overdose.

Less frequent side effects:

- grinding of teeth
- flushing (hot flush)
- night sweats.

The following side effects have been reported but the frequency for them to occur is not known:

- 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)
- bleeding, skin discolouration due to bruising, bleeding from the nose, teeth, gums, vaginal bleeding (symptoms of haemorrhage)

APPROVED PATIENT INFORMATION LEAFLET

- swelling of the lower layer of skin and tissue, skin rash, rash of round, red welts on the skin that itch intensely, sometimes with dangerous swelling (urticaria)
- bone fractures
- not wanting or able to perform sexual activity or enjoying sexual activity.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of VORTIOXETINE DYNA. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store VORTIOXETINE DYNA

Store all medicines out of reach of children.

Store at or below 25 °C

Keep tablets in blisters until time for use.

Keep blisters in the carton until required for use.

APPROVED PATIENT INFORMATION LEAFLET

Do not use after the expiry date stated on the carton. 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 DYNA contains

VORTIOXETINE 5 mg DYNA contains vortioxetine hydrobromide equivalent to 5 mg vortioxetine.

VORTIOXETINE 10 mg DYNA contains vortioxetine hydrobromide equivalent to 10 mg vortioxetine.

VORTIOXETINE 20 mg DYNA contains vortioxetine hydrobromide equivalent to 20 mg vortioxetine.

The other ingredients are:

Tablet cores:

Colloidal silicon dioxide, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate.

Film coating – Opadry White

HPMC 2910/Hypromellose, macrogol/PEG, titanium dioxide.

What VORTIOXETINE DYNA looks like and contents of the pack

APPROVED PATIENT INFORMATION LEAFLET

VORTIOXETINE 5 mg DYNA are white coloured, round shaped, biconvex, film-coated tablets debossed with "V" on one side and "5" on other side.

VORTIOXETINE 10 mg DYNA are white coloured, almond shaped, biconvex, film-coated tablets debossed with "V" on one side and "10" on other side.

VORTIOXETINE 20 mg DYNA are white coloured, almond shaped, biconvex, film-coated tablets debossed with "V" on one side and "20" on other side.

30's pack: 10 tablets of VORTIOXETINE DYNA Tablets 5 mg, 10 mg and 20 mg are sealed with PVC/PVdC base foil on one side and Aluminium lid foil on other side in the form of Alu-PVC/PVdC blister and 3 x blister packs are further packed in a printed carton.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

This leaflet was last revised in

Registration date: 16 May 2023

Registration numbers

VORTIOXETINE 5 mg DYNA: A55/1.2/0108.105

Vortioxetine 5 mg 10 mg and 20 mg tablets
Pharma Dynamics (Pty) Ltd

Each film coated tablets contains either
5 mg, 10 mg or 20 mg vortioxetine

APPROVED PATIENT INFORMATION LEAFLET

VORTIOXETINE 10 mg DYNA: A55/1.2/0109.106

VORTIOXETINE 20 mg DYNA: A55/1.2/0110.107