PATIENT INFORMATION LEAFLET

BRIVOR RANGE

SCHEDULING STATUS

S5

BRIVOR 5 mg film coated tablets

BRIVOR 10 mg film coated tablets

BRIVOR 20 mg film coated tablets

Vortioxetine

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

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

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

Read all of this leaflet carefully before you start taking BRIVOR

- 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.
- BRIVOR 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 BRIVOR is and what it is used for
2. What you need to know before you take BRIVOR
3. How to take BRIVOR
4. Possible side effects
5. How to store BRIVOR
6. Contents of the pack and other information

1. What BRIVOR is and what it is used for

BRIVOR 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.

BRIVOR is used to treat major depressive episodes in adults.

2. What you need to know before you take BRIVOR

Do not take BRIVOR:

- if you are hypersensitive (allergic) to vortioxetine, or to any of the ingredients of BRIVOR (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 BRIVOR:

- 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 BRIVOR, 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
  - 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
  - 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 BRIVOR 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
- 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

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

Other medicines and BRIVOR

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

- rifampicin (a medicine to treat tuberculosis and other infections) as your dose of BRIVOR may be adjusted
- carbamazepine, phenytoin (medicines to treat epilepsy or other illness) as your dose of BRIVOR may be adjusted
- warfarin, dipyridamole, phenprocoumon, low-dose acetylsalicylic acid (blood thinning medicines)
- lithium or tryptophan (medicine to treat depression and mental disorders) as the effect of BRIVOR may be enhanced.

BRIVOR with food and drink

BRIVOR 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, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using BRIVOR.

BRIVOR should not be used during pregnancy.

Breastfeeding

It is expected that the ingredients of BRIVOR will pass into breast milk. BRIVOR is not to be used during breast-feeding. Your doctor will make a decision on whether you should stop breastfeeding or stop using BRIVOR taking into account the benefit of breastfeeding for your child, and the benefit of therapy for you.

Driving and using machines

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

It is not always possible to predict to what extent BRIVOR 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 BRIVOR affects you.

Excipients with a known effect

BRIVOR contains mannitol which may have a mild laxative effect.

3. How to take BRIVOR

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

***Adults**:*

The recommended dose of BRIVOR is 10 mg taken as a once 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:

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

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

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

If you take more BRIVOR 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.

Symptoms of overdose may include:

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

If you forget to take BRIVOR:

If you forget to take BRIVOR, 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 BRIVOR

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

4. Possible side effects

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

If any of the following happens, stop using BRIVOR 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 BRIVOR. 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:

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 of 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)
- 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, pharmacist or nurse. You can also report any 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 BRIVOR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store BRIVOR

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.

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 BRIVOR contains

BRIVOR 5 mg contains vortioxetine hydrobromide equivalent to 5 mg vortioxetine.

BRIVOR 10 mg contains vortioxetine hydrobromide equivalent to 10 mg vortioxetine.

BRIVOR 20 mg 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 BRIVOR looks like and contents of the pack

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

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

BRIVOR 20 mg 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 BRIVOR 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

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