PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

BRINTELLIX 5 mg, 10 mg, 15 mg and 20 mg film-coated tablets

Vortioxetine

Read all of this leaflet carefully before you start taking BRINTELLIX

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

BRINTELLIX belongs to a group of medicines called antidepressants. BRINTELLIX is used to treat major depressive episodes in adults.

2. What you need to know before you take BRINTELLIX

Do not take BRINTELLIX

- if you are allergic to vortioxetine or any of the other ingredients of this medicine (see What brintellix contains)
- if you are taking other medicines for depression such as monoamine oxidase inhibitors. Ask your doctor if you are uncertain.

Warnings and special precautions

Talk to your doctor or pharmacist before taking BRINTELLIX if you:

- are taking medicines with a so-called serotonergic effect, such as:
  - tramadol (a strong painkiller)
  - sumatriptan and similar medicines to BRINTELLIX with active
  - substance names ending in “triptans” (used to treat migraine).

  Taking these medicines together with BRINTELLIX may cause serotonin syndrome. This syndrome may be associated with hallucinations (distorted perception), involuntary twitching, accelerated heartbeat, high blood pressure, fever, nausea and diarrhoea.
- have had fits

  Your doctor will treat you cautiously if you have a history of fits or have unstable fit disorders/epilepsy. You should stop taking BRINTELLIX if you develop fits or if there is an increase in the frequency of fits.
- have had mania (elevated mood)
- have a tendency to easily develop bleedings or bruises
- are elderly
- have a liver disease called cirrhosis
- have low sodium level in the blood
- are treated with other medicines known to cause low sodium level.

Thoughts of suicide and worsening of your depression

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 to take BRINTELLIX, since it takes 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 such as BRINTELLIX.

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.

Children and adolescents

BRINTELLIX is not recommended in children and adolescents under 18 years.

Other medicines and BRINTELLIX

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

Also tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- moclobemide (a medicine to treat depression)
- selegiline, rasagiline (a medicine to treat Parkinson’s disease)
- phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine

  (medicines to treat depression called monoamine oxidase inhibitors)

you must not take any of these medicines together with Brintellix.

If you have taken any of these medicines you will need to wait 14 days before you start taking BRINTELLIX. After stopping BRINTELLIX you must allow 14 days before taking any of these medicines.

- linezolid (a medicine to treat bacterial infections)
- lithium (a medicine to treat depression and mental disorders) or tryptophan
- medicines that increase the risk of fits; sumatriptan and similar medicines to BRINTELLIX with active substance names ending in “triptans”
- tramadol (a strong painkiller)
- mefloquin (a medicine to prevent and treat malaria)
- bupropion (a medicine to treat depression and also used to wean from smoking)
- fluoxetine, paroxetine and other medicines to treat depression called SSRI/SNRIs, tricyclics
- St John’s Wort (a medicine to treat depression)
- quinidine (a medicine to treat heart rhythm disorders)
- medicines to treat mental disorders and belongs to the groups called phenothiazines, thioxanthenes, butyrophenones
- rifampicin (a medicine to treat tuberculosis)
- carbamazepine, phenytoin (medicines to treat epilepsy or other illness)
- Warfarin and low-dose aspirin (blood thinning medicines)

BRINTELLIX with food, drink and alcohol

BRINTELLIX can be taken with or without food.

Combining BRINTELLIX with alcohol is not advisable.

Pregnancy and breastfeeding

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 BRINTELLIX.

Pregnancy

BRINTELLIX should not be used during pregnancy as it may harm your baby.

If you are of childbearing age you should use effective contraception while taking BRINTELLIX.

The following effects may be seen in your newborn baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties.

BRINTELLIX may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

Breastfeeding

Mothers should not breastfeed their infants when taking BRINTELLIX.

Driving and using machines

As adverse reactions such as dizziness have been reported, caution is advised when driving and using machines when beginning BRINTELLIX treatment or changing the dose.

3. How to take BRINTELLIX

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

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

The normally recommended dose of BRINTELLIX is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg 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 of BRINTELLIX is 5 mg taken once daily. Do not change the dose of your medicine without talking to your doctor first.

Take one tablet with a glass of water.

The tablet can be taken with or without food.

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

Use in children and adolescents

BRINTELLIX is not for use in children and adolescents under 18 years.

Duration of treatment

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

Take BRINTELLIX for as long as your doctor recommends.

Continue to take BRINTELLIX even if it takes some time before you feel any improvement in your condition.

Treatment should be continued for at least 6 months after you feel well again.

If you take more BRINTELLIX 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.

Have the container and any remaining tablets available. Do this even if there are no signs of discomfort.

Overdose signs are dizziness, nausea, diarrhoea, stomach discomfort, itching of the whole body, sleepiness and flushing.

Following intake of dosages several times higher than the prescribed dose, fits (seizures) and a rare condition called serotonin syndrome have been reported.

If you forget to take BRINTELLIX

Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking BRINTELLIX

Do not stop taking BRINTELLIX without talking with your doctor.

If you have any further questions on the use of BRINTELLIX, ask your doctor or pharmacist.

4. Possible side effects

BRINTELLIX can cause side effects.

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

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

- swelling of the face, lips, tongue or throat
- difficulties in breathing or swallowing
- rash or itching
- a sudden drop in blood pressure (making you feel dizzy or lightheaded).

These are all very serious side effects. If you have them, you may have had a serious reaction to BRINTELLIX. You may need urgent medical attention or hospitalisation.

Side effects listed below have been reported by patients taking BRINTELLIX in the following frequencies:

Frequently:

- nausea

- diarrhoea, constipation, vomiting
- dizziness
- itching of the whole body
- abnormal dreams
- drowsiness, feeling tired

Less frequent:

- Flushing
- night sweats
- low levels of sodium in the blood (the symptoms may include feeling dizzy, weak, confused, sleepy or even very tired, or feeling of being sick; more serious symptoms are fainting, fits or falls).
- serotonin syndrome (see Warnings and special precautions)
- hives
- excessive or unexplained bleeding (including bruising, nose bleeding, gastrointestinal and vaginal bleeding).

You may experience less satisfaction with orgasm or sexual arousal, especially at the 20 mg BRINTELLIX dose.

An increased risk of bone fractures has been observed in patients taking this type of medicine.

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 the South African Health Products Regulatory Authority (SAHPRA) via the “6.04 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 BRINTELLIX

5. How to store BRINTELLIX

Store all medicines out of the reach of children.

Store at or below 30 °C.

Do not use BRINTELLIX after the expiry date which is stated on the packaging after 'EXP'. The expiry date refers to the last day of that month.

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 BRINTELLIX contains

The active substance is vortioxetine.

Each BRINTELLIX 5 mg tablet contains vortioxetine hydrobromide equivalent to 5 mg vortioxetine.

Each BRINTELLIX 10 mg tablet contains vortioxetine hydrobromide equivalent to 10 mg vortioxetine.

Each BRINTELLIX 15 mg tablet contains vortioxetine hydrobromide equivalent to 15 mg vortioxetine.

Each BRINTELLIX 20 mg tablet contains vortioxetine hydrobromide equivalent to 20 mg vortioxetine.

The other ingredients are:

Tablet core: Hydroxypropylcellulose, mannitol, magnesium stearate, microcystalline cellulose, sodium starch glycolate (type A).

Tablet coating: Hypromellose, Macrogol 400, titanium dioxide (E171), Iron oxide red (E172) (5, 15 and 20 mg tablets), Iron oxide yellow (E172) (10 and 15 mg tablets).

What BRINTELLIX looks like and contents of the pack

5 mg: Pink, almond-shaped film-coated tablet engraved with “TL” on one side and “5” on the other side.

10 mg: Yellow, almond-shaped film-coated tablet engraved with “TL” on one side and “10” on the other side.

15 mg: Orange, almond-shaped film-coated tablet engraved with “TL” on one side and “15” on the other side.

20 mg: Red, almond-shaped film-coated tablet engraved with “TL” on one side and “20” on the other side.

BRINTELLIX 5 mg, 10 mg, 15 mg and 20 mg film-coated tablets are presented in transparent, colourless PVC /PVdC/aluminium blister packaging. The blister cards are packed in printed cardboard cartons containing 28 tablets per pack.

Holder of the Certificate of Registration

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Registration numbers

5 mg: 48/1.2/0429

10 mg: 48/1.2/0430

15 mg: 48/1.2/0431

20 mg: 48/1.2/0432

Namibia and Botswana, only:

Botswana: S2: BOT 1502705 (10 mg); BOT 1502706 (20 mg)
Namibia: NS 3: 15/1.2/0071 (10 mg); 15/1.2/0072 (20 mg)