

BRINTELLIX Film-coated Tablets

Vortioxetine (5mg, 10mg, 15mg and 20mg)

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What Brintellix is used for

Brintellix is used to treat major depressive episodes in adults.

How Brintellix works

Brintellix contains the active substance vortioxetine. It belongs to a group of medicines called antidepressants. Brintellix 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.

Before you use Brintellix

When you must not use it

- if you are allergic to vortioxetine or any of the other ingredients of this medicine (listed in section Product Description).
- if you are taking other medicines for depression known as non-selective monoamine oxidase inhibitors or selective MAO-A inhibitors. Ask your doctor if you are uncertain.

Before you start use it

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

- are taking medicines with a so-called serotonergic effect, such as:
 - tramadol and similar medicines (strong painkillers).
 - sumatriptan and similar medicines 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, involuntary twitching, accelerated heartbeat, high blood pressure, fever, nausea and diarrhoea.

- 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.
- have had mania
- have a tendency to bleed or bruise easily, or if you are pregnant (See ‘Pregnancy, breast-feeding and fertility’). have low sodium level in the blood.
- are 65 years of age or older.
- have a severe kidney disease.
- have a severe liver disease or a liver disease called cirrhosis.
- 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.

When you are on antidepressant treatment, including vortioxetine, you may also experience feelings of aggression, agitation, anger and irritability. If this occurs, you should talk to your doctor.

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 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.

Children and adolescents:

Brintellix should not be used in paediatric patients (under 18 years of age) because efficacy has not been demonstrated. The safety of Brintellix in children and adolescents aged 7 to 17 years is described in “Side effects”.

Taking other medicines

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:

- phenelzine, iproniazid, isocarboxazid, nialamidetranylcypromine (medicines to treat depression called non-selective 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:
- moclobemide (a medicine to treat depression).
- selegiline, rasagiline (medicines to treat Parkinson’s disease).
- linezolid (a medicine to treat bacterial infections).
- medicinal products with serotonergic effect e.g. tramadol and similar medicines (strong painkillers) and sumatriptan and similar medicines with active substance names ending in “triptans” (used to treat migraine). Taking these medicines together with Brintellix may increase the risk of serotonin syndrome (see section warnings and precautions)
- lithium (a medicine to treat depression and mental disorders) or tryptophan.
- medicines known to cause low sodium level.
- rifampicin (a medicine to treat tuberculosis and other infections).

- carbamazepine, phenytoin (medicines to treat epilepsy or other illness).
- warfarin, dipyridamole, phenprocoumon, some antipsychotics, phenothiazines, tricyclic antidepressants, low-dose acetylsalicylic acid and non-steroidal anti-inflammatory drugs (blood thinning medicines and medicines used for pain relief). These may increase bleeding-tendency.

Medicines that increase the risk of fits:

- sumatriptan and similar medicines 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 also used to wean from smoking).
- fluoxetine, paroxetine and other medicines to treat depression called SSRI/SNRIs, tricyclics.
- St John's wort (*hypericum perforatum*) (a medicine to treat depression).
- quinidine (a medicine to treat heart rhythm disorders).
- chlorpromazine, chlorprothixene, haloperidol (medicines to treat mental disorders belonging to the groups called phenothiazines, thioxanthenes, butyrophenones).

Please tell your doctor if you are taking any of the medicines above, since your doctor needs to know if you already are at risk for seizures.

If you are having a urine drug screen, taking Brintellix may cause positive results for methadone when some test methods are used, even though you may not be taking methadone. If this happens, a more specific test can be performed.

Brintellix with alcohol:

Combining this medicine with alcohol is not advisable.

How to use Brintellix

How much to use

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

The recommended dose of Brintellix is 10 mg vortioxetine 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 vortioxetine 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.

When to use it

Take one tablet with a glass of water. The tablet can be taken with or without food.

How long to use it

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 forget to use it

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

If you use too much (overdose)

If you take more than the prescribed dose of Brintellix, contact your doctor or nearest hospital emergency department immediately. 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

While you are using it

Things you must do

- Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Side effects.

Things you must not do

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- Do not stop taking Brintellix without talking with your doctor.

Your doctor may decide to reduce your dose before you finally stop taking this medicine.

Some patients who stop taking Brintellix have experienced symptoms such as dizziness, headache, tingling feelings like pins and needles or electric shock-like feelings (particularly in the head), inability to sleep, feeling sick or vomiting, feeling anxious, irritable or agitated, feeling tired or shaking. These symptoms may occur within the first week after stopping Brintellix.

Things to be careful of

Pregnancy, breast-feeding and fertility: If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy:

Brintellix should not be used during pregnancy unless the doctor says it is absolutely necessary.

If you take medicines to treat depression, including Brintellix, during the last 3 months of your pregnancy, you should be aware that 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. Contact your doctor immediately if your newborn baby has any of these symptoms. Make sure your midwife and/or doctor know you are on Brintellix. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like 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.

If you take Brintellix near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Brintellix so they can advise you.

Breast-feeding:

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

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Driving and using machines

Brintellix 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 Brintellix treatment or changing the dose.

Brintellix contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In general, the observed side effects were mild to moderate and occurred within the first two weeks of treatment. The reactions were usually temporary and did not lead to cessation of therapy. Side effects listed below have been reported in the following frequencies.

Very common: may affect more than 1 in 10 people

- nausea

Common: may affect up to 1 in 10 people

- diarrhoea, constipation, vomiting
- dizziness
- itching of the whole body
- abnormal dreams
- increased sweating
- indigestion

Uncommon: may affect up to 1 in 100 people

- flushing
- night sweats
- blurred vision
- involuntary shaking (tremor)

Rare: may affect up to 1 in 1,000 people

- enlarged pupils (mydriasis), which can increase the risk of glaucoma (see "Before you start use it")

Not known: frequency cannot be estimated from available data

- 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
- allergic reactions, that may be serious, causing swelling of the face, lips, tongue or throat, difficulties breathing or swallowing, and/or a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- hives
- excessive or unexplained bleeding (including bruising, nose bleeding, gastrointestinal and vaginal bleeding)
- rash
- sleep disorders (insomnia)
- agitation and aggression. If you experience these side effects, contact your doctor (see "Before you start use it").
- headache
- increase in a hormone called prolactin in the blood
- a constant urge to move (akathisia)
- grinding one's teeth (bruxism)
- inability to open your mouth (lockjaw/trismus)
- restless leg syndrome (urges to move the legs to stop painful or odd sensations, often occurring at night)
- abnormal milky discharge from the breast (galactorrhoea)

An increased risk of sexual dysfunction has been reported with the 20 mg dose, and in some patients this side effect was observed at lower doses.

Additional side effects in children and adolescents

Side effects observed with vortioxetine in children and adolescents were similar to those seen for adults except for abdominal pain related events that were observed more often in adolescents than in adults and suicidal thoughts that were observed more often in adolescents than in adults.

Reporting of side effects

If you get any 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 directly via the national reporting system. By reporting side effects, you

can help provide more information on the safety of this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website www.npra.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))).

Storage and Disposal of Brintellix**Storage**

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date that is stated on the packaging after EXP. The expiry date refers to the last day of that month. Do not store above 30°C.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product Description**What it looks like****5 mg vortioxetine, film-coated tablet:**

Pink, almond-shaped 5 x 8.4 mm film-coated tablet marked with "TL" on one side and "5" on the other side.

Brintellix film-coated tablets 5 mg are available in blister packs of 14 and 28 tablets.

Not all pack sizes may be marketed.

10 mg vortioxetine, film-coated tablet:

Yellow, almond-shaped 5 x 8.4 mm film-coated tablet marked with "TL" on one side and "10" on the other side.

Brintellix film-coated tablets 10 mg are available in blister packs of 14 and 28 tablets.

Not all pack sizes may be marketed

15 mg vortioxetine, film-coated tablet:

Orange, almond-shaped 5 x 8.4 mm film-coated tablet marked with "TL" on one side and "15" on the other side.

Brintellix film-coated tablets 15 mg are available in blister packs of 14 and 28 tablets.

Not all pack sizes may be marketed.

20 mg vortioxetine, film-coated tablet:

Red, almond-shaped 5 x 8.4 mm film-coated tablet marked with "TL" on one side and "20" on the other side.

Brintellix film-coated tablets 20 mg are available in blister packs of 14 and 28 tablets.

Not all pack sizes may be marketed

Ingredients**5 mg vortioxetine, film-coated tablet:**

- Active ingredient: The active substance is vortioxetine. Each film-coated tablet contains 5 mg vortioxetine (as hydrobromide).
- Inactive ingredients: The other ingredients are mannitol (E421), microcrystalline cellulose, hydroxypropylcellulose, sodium starch glycolate (type A), magnesium stearate, hypromellose, Macrogol 400, titanium dioxide (E171), iron oxide red (E172).

10 mg vortioxetine, film-coated tablet:

- Active ingredient: The active substance is vortioxetine. Each film-coated tablet contains 10 mg vortioxetine (as hydrobromide).
- Inactive ingredients: The other ingredients are mannitol (E421), microcrystalline cellulose, hydroxypropylcellulose, sodium starch glycolate (type A), magnesium stearate, hypromellose, Macrogol 400, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172).

15 mg vortioxetine, film-coated tablet:

- Active ingredient: The active substance is vortioxetine. Each film-coated tablet contains 15 mg vortioxetine (as hydrobromide).
- Inactive ingredients: The other ingredients are mannitol (E421), microcrystalline cellulose, hydroxypropylcellulose, sodium starch glycolate (type A), magnesium stearate, hypromellose, Macrogol 400, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172).

20 mg vortioxetine, film-coated tablet:

- Active ingredient: The active substance is vortioxetine. Each film-coated tablet contains 20 mg vortioxetine (as hydrobromide).
- Inactive ingredients: The other ingredients are mannitol (E421), microcrystalline cellulose, hydroxypropylcellulose, sodium starch glycolate (type A), magnesium stearate, hypromellose, Macrogol 400, titanium dioxide (E171), iron oxide red (E172).

MAL number(s):

5mg: MAL15045161AZ

10mg MAL15045160AZ

15mg: MAL15045162AZ

20mg: MAL15045163AZ

Manufacturer

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