Package leaflet: Information for the patient

Brintellix 5 mg film-coated tablets
Brintellix 10 mg film-coated tablets
Brintellix 15 mg film-coated tablets
Brintellix 20 mg film-coated tablets
vortioxetine

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.
- 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Brintellix is and what it is used for

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

Brintellix is used to treat major depressive episodes in adults.

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.

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 (listed in section 6).
- 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.

Warnings and 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 with active substance names ending in “triptans” (used to treat migraine).

  Taking these medicines together with Brintellix may increase the risk of 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.
- 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.

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

Other medicines and Brintellix

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, nialamide, tranylcypromine (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).
- lithium (a medicine to treat depression and mental disorders) or tryptophan.
- medicines know 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, low-dose acetylsalicylic acid (blood thinning medicines).

Medicines that increase the risk of fits:
- sumatriptan and similar medicines with active substance names ending in "triptans".
- tramadol (a strong painkiller).
- mefloquine (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.

Brintellix with alcohol

Combining this medicine with alcohol is not advisable.

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.

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.

Driving and using machines

Brintellix has no or negligible influence on the ability to drive and use machines. However, as adverse reactions such as diziness have been reported, caution is advised during such activities when beginning Brintellix treatment or changing the dose.

3. How to take Brintellix

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.

Method of administration

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

Duration of treatment

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

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.

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 this medicine, ask your doctor or pharmacist.

4. Possible 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

Uncommon: may affect up to 1 in 100 people
- flushing
- night sweats

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 (see section 2)
- swelling of the face, lips, tongue or throat
- hives

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

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:

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie

e-mail: medsafety@hpra.ie
United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Brintellix

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.

This medicine does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Brintellix contains

- The active substance is vortioxetine.
  Each 5 mg film-coated tablet contains 5 mg vortioxetine (as hydrobromide).
  Each 10 mg film-coated tablet contains 10 mg vortioxetine (as hydrobromide).
  Each 15 mg film-coated tablet contains 15 mg vortioxetine (as hydrobromide).
  Each 20 mg film-coated tablet contains 20 mg vortioxetine (as hydrobromide).
- 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) (5 mg, 15 mg and 20 mg tablets only)
  iron oxide yellow (E172) (10 mg and 15 mg tablets only)

What Brintellix looks like and contents of the pack

5 mg tablets: Pink, almond-shaped 5 x 8.4 mm film-coated tablet marked with “TL” on one side and “5” on the other side.
10 mg tablets: Yellow, almond-shaped 5 x 8.4 mm film-coated tablets marked with “TL” on one side and “10” on the other side.
15 mg tablets Orange, almond-shaped 5 x 8.4 mm film-coated tablet marked with “TL” on one side and “15” on the other side.

20 mg tablets: 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 5 mg are available in blister packs of 14, 28, 98, 56x1, 98x1, 126 (9 x 14), 490 (5 x (98x1)) tablets and in tablet containers of 100 and 200 tablets.
Brintellix film-coated tablets 10 mg are available in blister packs of 7, 14, 28, 56, 56 x 1, 98, 98x1, 126 (9 x 14), 490 (5 x (98x1)) tablets and in tablet containers of 100 and 200 tablets.
Brintellix film-coated tablets 15 mg are available in blister packs of 14, 28, 56, 56 x 1, 98, 98x1, 490 (5 x (98x1)) tablets and in tablet containers of 100 and 200 tablets.
Brintellix film-coated tablets 20 mg are available in blister packs of 14, 28, 56, 56x1, 98, 98x1, 126 (9 x 14), 490 (5 x (98x1)) tablets and in tablet containers of 100, 200 tablets.

The pack sizes of 56 x 1, 98 x 1 and 490 film-coated tablets are presented in unit dose blister.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

H. Lundbeck A/S
Ottiliavej 9
2500 Valby
Denmark

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland
Lundbeck (Ireland) Limited
Tel: +353 468 9800

United Kingdom
Lundbeck Limited
Tel: +44 1908 64 9966

Malta
H. Lundbeck A/S
Tel: + 45 36301311

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Other sourses of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.