

Your guide to **Brintellix**[®] (vortioxetine)



If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can report side effects directly to HPRA (Health Products Regulatory Authority) at: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

This leaflet has been developed by Lundbeck for patients prescribed Brintellix only.



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This leaflet will give you an overview of Brintellix®, including information about what it is, how to take it and possible side effects that you may experience.

Further information about this medicine is available in the patient information leaflet that comes with your prescription. If you ever have concerns about **any medication** you are taking, you should always raise these with your doctor.

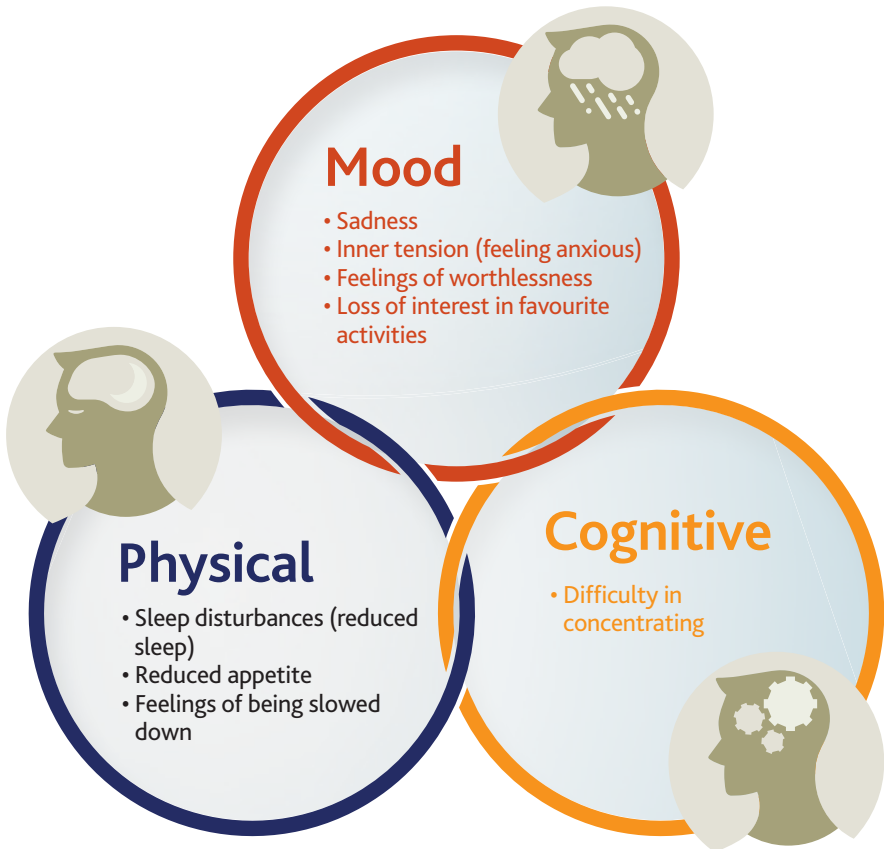


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What is Brintellix®?

Brintellix is an antidepressant that is used to treat major depressive episodes in adults. It contains an active substance called vortioxetine and has been shown to improve a broad range of depressive symptoms including:



If you would like more information on depression, please visit the information page on Lundbeck.ie or you can contact Aware using the contact details contained in this leaflet.

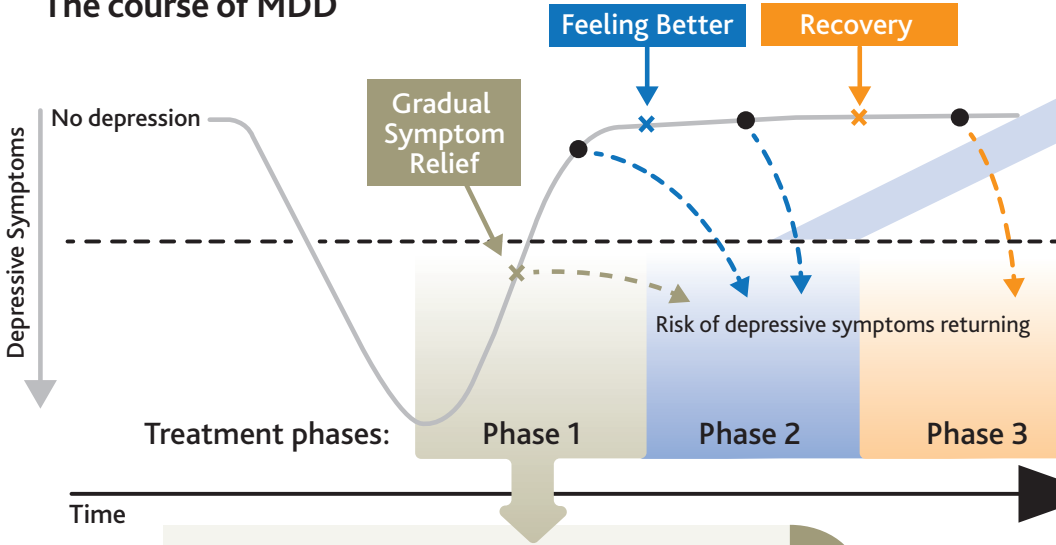


Why should I take this medicine?

Taking the antidepressant treatment that is prescribed by your doctor greatly increases the chances of feeling well again. Feeling well again may involve improvements in all groups of depressive symptoms: mood, physical and cognitive, enabling you to deal more effectively with day to day activities. Treatment should be continued for at least 6 months after you feel well again to maximize the potential for you to stay well.

The graph below illustrates how the symptoms of depression typically change with time. As your individual experience of depression may vary from that shown in the graph, it is important to always keep in touch with and follow the advice of your doctor.

The course of MDD




Phase I: Getting started

After starting your medicine you will not feel better immediately as all medicines for depression take some time to work. You should experience gradual relief from depressive symptoms over several weeks. Contact your doctor if you do not feel better or if you are concerned about side effects.






Phase 2: Keeping going



As you continue to feel better, carry on taking the treatment continuously at the dose advised by your doctor. Do not stop your medicine abruptly. Keep following the lifestyle advice given by your doctor and continue to access any support provided by friends and family and psychological services. Your medicine relieves the symptoms of depression but accessing these supports will help you to address its causes.

Phase 3: Feeling back to yourself



You will now have been feeling better for several months with the symptoms of depression greatly reduced or completely resolved and a return to enjoying your normal activities. Your doctor may recommend that you discontinue your medicine for depression, or depending on how you are feeling, your medical history and the risk of a new episode of depression occurring, he or she may advise you to continue your medicine, as this will greatly decrease the risk of your depressive symptoms returning.



How does vortioxetine work?

Depression is a complex condition with causes related to both biological and environmental reasons. Depression may result from triggers such as illness, grief or a build-up of stresses and strains of daily life. In some cases there are no obvious triggers. Depression may be associated with an imbalance of brain neurotransmitters and Brintellix and other antidepressants work by correcting this imbalance.

How long will vortioxetine take to work?

After starting your medicine, you will not feel better immediately, as all medicines for depression take some time to work. Some patients may start to notice improvements after about 2 weeks, but in other patients this may take longer.

If you are not feeling better (or have begun to feel worse) after 4–6 weeks of treatment, or if side effects are unmanageable, go back to your doctor to get advice about changing your dose or about finding a more suitable alternative treatment.

What else can I do?

You can speak to your doctor who will be able to provide lifestyle information particularly around the value of a healthy diet and daily exercise. Additionally, you can ask your doctor about talk therapies such as counseling or cognitive behavioral therapy (CBT). Problems don't go away just because you ignore them. It is better to confront them before they become bigger.

When your mood is low, you may find it helpful to:

- Speak to a trusted friend or family member
- Attend a support group
- Develop coping techniques such as relaxation and rationalisation to help with unrealistically negative thoughts



How do I take this medicine?

Please read the patient information leaflet contained within the Brintellix pill packet thoroughly when you begin your treatment.

Tablets should be swallowed whole with a glass of water, once a day, with or without food.

Always take this medicine exactly as your doctor has told you to.

Do not change your dose or stop taking your medication without talking to your doctor.

It is important to continue taking Brintellix according to the recommendations of your doctor, even if it takes some time before you start to feel better. Treatment should be continued for at least 6 months after you feel well again.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the medicines listed in the *Other medicines and Brintellix* section of the patient information leaflet.



- If you take more medication than you should, call your doctor or hospital straight away



- If you forget to take your Brintellix, take your next dose at the usual time. Do not take a double dose to make up for the missed dose

Warnings and Precautions

Do not take vortioxetine:

- if you are allergic to vortioxetine or any other ingredients of the medicine (listed within the Patient Information Leaflet)
- if you are taking non-selective monoamine oxidase inhibitors or selective MAO-A inhibitor antidepressants. Ask your doctor if you are uncertain.

Talk to your doctor or pharmacist before taking vortioxetine:

- if have any of the conditions listed in the *Warnings and precautions* section of the patient information leaflet.



What side effects have been reported with vortioxetine?

As with all medications Brintellix can cause side effects, although you won't necessarily experience them.

In general, side effects are mild to moderate and occur within the first two weeks of treatment. The reactions are usually temporary and do not typically lead to patients having to stop their treatment. The most common side effect with Brintellix (experienced by more than 1 in 10 people) is nausea (feeling sick).

Very Common (more than 1 in 10 people) and Common (up to 1 in 10 people) side effects of Brintellix:



Nausea (very common),
Diarrhoea, Constipation,
Vomiting (common)



Abnormal dreams



Dizziness



Itching of the whole
body



Dyspepsia
(indigestion)



Hyperhidrosis (abnormally excessive
sweating that's not necessarily
related to heat or exercise)

See the Patient Information Leaflet for further information about possible side effects.



Important safety information

If you are depressed, you may experience thoughts of self-harm. These may increase when first starting a course of some antidepressant treatments, including Brintellix®, as these medicines all take time to work. You may notice improvements after about two weeks, but some medicines may take longer.

If at any time you have feelings or thoughts of self-harm while taking this medicine, 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 for help. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Patients who have had thoughts of self-harm prior to starting treatment and young adults (less than 25 years old) may be more likely to experience thoughts of self-harm when first starting treatment, or following a change in the dose of their medicine.



What else is important to know?



Can I drive?

This medicine is not expected to influence your ability to drive or use machinery. However, as side effects such as dizziness have been reported, it is recommended that you take extra care when driving or using machines if you have only just started to take Brintellix or if the amount you are taking has recently changed.

Can I take this medicine while pregnant or breastfeeding?

This medicine is not recommended to be taken during pregnancy, unless your doctor thinks it is absolutely necessary. If you are pregnant and taking Brintellix, make sure your midwife and medical team know.

Brintellix is also not recommended for use if you are breastfeeding.

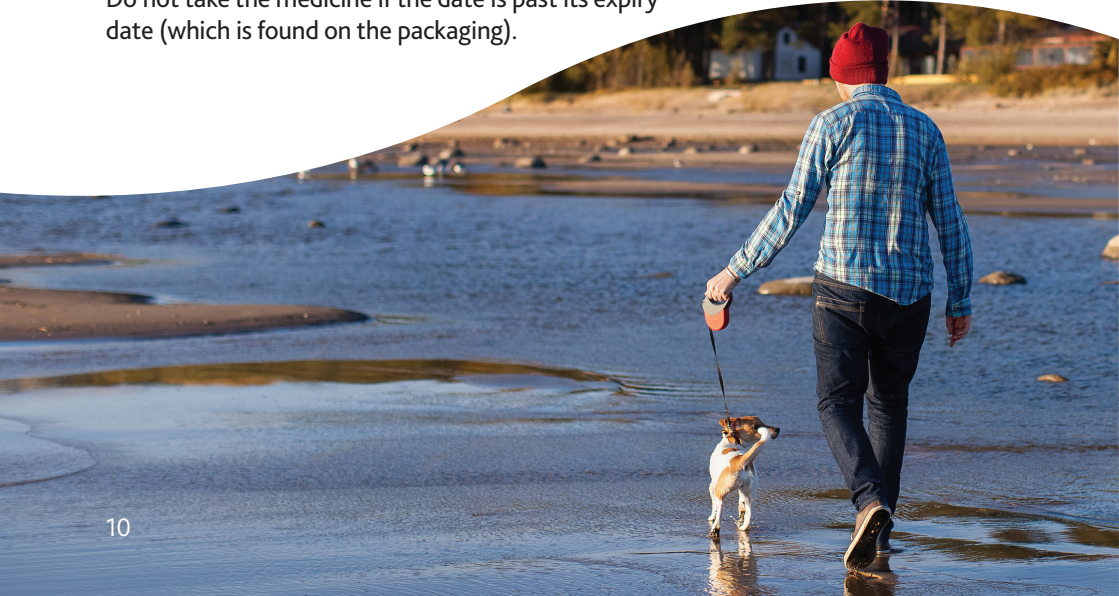
What if I have any questions?

Please consult your doctor or pharmacist for further information about depression and your treatment.

How do I store this medicine?

You don't need to store this medicine in any special way, however it should be kept out of the sight and reach of children.

Do not take the medicine if the date is past its expiry date (which is found on the packaging).



Where can I find further support?

Talking to friends and family can often provide a source of comfort and support if you are struggling with your depression or treatment. However, if you feel like you need some extra support, the organisation below may be able to help:



AWARE

Aware is a national organisation which provides a range of support, education and information services around depression. See www.aware.ie for a full list of services including:

Support
Line

1800 80 48 48

Support
Mail

supportmail@aware.ie

Support
Groups

www.aware.ie

Aware offers a free evidence based programme based on the principles of Cognitive Behavioural Therapy (CBT) which can be helpful in managing the symptoms of mild to moderate depression. The Life Skills Programme is available in virtual and group settings. More information on the programme and details on how to register is available on the Aware website. Aware also runs a free monthly webinar series featuring expert speakers on a range of topics relating to mental health. An archive of webinars and lectures are available to listen back, or to view, on the website.

Please note that Aware does not offer specific advice in relation to this medicine, but the additional support that is available through the organisation's services may provide further help to you as you manage your experience of depression.

You can also speak to your doctor or nurse for information on local support groups that may be available within your area.



References: 1. Brintellix Package Leaflet accessed on medicines.ie 2. Taylor DM, Barnes TRE, Young AH, The Maudsley Prescribing Guidelines in Psychiatry, 14th Edition, June 2021 (page 376) 3. Depression Curve adapted from Kupfer. *J Clin Psychiatry* 1991; 52 (Suppl 5):28-34.

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