



Package leaflet: Information for the patient

Vortioxetine 5 mg Film-Coated Tablets
Vortioxetine 10 mg Film-Coated Tablets
Vortioxetine 15 mg Film-Coated Tablets
Vortioxetine 20 mg Film-Coated Tablets

(Vortioxetine)

Warning – Thoughts of self- harm and suicidal behaviour – see section 2

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.

The name of your medicine is “Vortioxetine Film-Coated Tablets” but will be referred as “Vortioxetine” in this leaflet.

What is in this leaflet

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

1. What Vortioxetine is and what it is used for

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

Vortioxetine is used to treat major depressive episodes in adults.

Vortioxetine 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 Vortioxetine

Do not take Vortioxetine:
- 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 Vortioxetine 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 Vortioxetine 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, 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

This medicine may be associated with thoughts of self-harm and suicidal behaviour in some people.

Tell someone you trust, who can help you in an emergency, that you are taking this medicine and ask that they read this leaflet

Talk to your trusted person, prescriber or go to a hospital straight away, if after starting this medicine, you have new or worse:
- Feelings of anxiety or irritability
- Feelings of restlessness and agitation
- Extreme increases in activity and difficulty sleeping
- Thoughts of acting on dangerous impulses to harm yourself
- Thoughts about suicide or dying
- Changes in behaviour or mood you, or someone you trust, notices and is worried about

In some people, thoughts of self-harm and suicidal behaviour may be increased when first starting antidepressants. Antidepressants take time to work; and sometimes side effects occur before you or others notice improvements in your mood.

Never stop taking an antidepressant suddenly without first talking to a healthcare professional. Stopping an antidepressant medicine suddenly can cause other symptoms related to withdrawal to occur.

Information from clinical trials has shown the highest risk of thoughts of self harm and suicidal behaviour, is in adults aged less than 25 years who were treated with an antidepressant but the risk applies to people of all ages treated with these medicines.

Call NHS 111 who can offer you support, until you can be with someone who can help you in person.

Children and adolescents

Vortioxetine should not be used in paediatric patients (under 18 years of age) because efficacy has not been demonstrated. The safety of Vortioxetine in children and adolescents aged 7 to 17 years is described in section 4.

Other medicines and Vortioxetine

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 Vortioxetine. If you have taken any of these medicines, you will need to wait 14 days before you start taking Vortioxetine. After stopping Vortioxetine 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 Vortioxetine 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).
- 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.

If you are having a urine drug screen, taking Vortioxetine 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.

Vortioxetine 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

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

If you take medicines to treat depression, including Vortioxetine, 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 Vortioxetine. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Vortioxetine 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 Vortioxetine 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 Vortioxetine so they can advise you.

Breast-feeding

A small amount of Vortioxetine will pass into breast milk, but no harmful, drug-associated effects have been observed in the infants. Vortioxetine is not to be used during breast-feeding. Your doctor will make a decision on whether you should stop breast-feeding or stop using Vortioxetine 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
Vortioxetine 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 Vortioxetine treatment or changing the dose.

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

3. How to take Vortioxetine
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 Vortioxetine 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 Vortioxetine for as long as your doctor recommends.

Continue to take Vortioxetine 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 Vortioxetine than you should
If you take more than the prescribed dose of Vortioxetine, 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 could be 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 Vortioxetine
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 Vortioxetine
Do not stop taking Vortioxetine 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 Vortioxetine 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 Vortioxetine.

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
- increased sweating
- indigestion

Uncommon: may affect up to 1 in 100 people
- flushing
- night sweats
- blurred vision
- involuntary shaking (tremor)
- hallucinations (seeing, hearing or feeling things that are not there)

Rare: may affect up to 1 in 1,000 people
- enlarged pupils (mydriasis), which can increase the risk of glaucoma (see section 2)

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)
- 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 section 2)
- 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)
- sexual dysfunction

An increased risk of bone fractures has been observed in patients taking this type of medicines.
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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: **www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.**

5. How to store Vortioxetine
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 Vortioxetine contains
- The active substance is vortioxetine. Each film-coated tablet contains 5, 10, 15 or 20 mg vortioxetine (as hydrobromide).
- The other ingredients are Cellulose, Microcrystalline, Mannitol (E421), Hydroxypropyl Cellulose (E463), Sodium Starch Glycolate (type A), Magnesium Stearate, Hypromellose, Titanium Dioxide (E171), Macrogol, Iron Oxide Yellow (E172), Iron Oxide Red (E172).

What Vortioxetine looks like and contents of the pack
Vortioxetine 5 mg film-coated tablet

Peach to Pink colored, Oval shaped, Biconvex, beveled edge, Film coated tablets, debossed "5" on one side and plain on other side. The tablet should free of all physical defects.

The tablet length is approx. 6 mm and width is approx. 4 mm.

Vortioxetine 10 mg film-coated tablet

Peach to Pink colored, Oval shaped, Biconvex, beveled edge, Film coated tablets, debossed "10" on one side and plain on other side. The tablet should free of all physical defects.

The tablet length is approx. 9 mm and width is approx. 5 mm

Vortioxetine 15 mg film-coated tablet

Peach to Pink colored, Oval shaped, Biconvex, beveled edge, Film coated tablets, debossed "15" on one side and plain on other side. The tablet should free of all physical defects.

The tablet length is approx. 10.5 mm and width is approx. 5.3 mm.

Vortioxetine 20 mg film-coated tablet

Peach to Pink colored, Oval shaped, Biconvex, beveled edge, Film coated tablets, debossed "20" on one side and plain on other side. The tablet should free of all physical defects.

The tablet Length is approx. 11 mm and width is approx. 6.5 mm.

Vortioxetine film-coated tablets are available in blister packs of 7, 14, 28, 56, 98, 126, 490 tablets.

Not all strengths and/or pack sizes may be marketed.

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