PACKAGE LEAFLET

Package leaflet: Information for the user

Qerrassa 5 mg filmomhulde tabletten
Qerrassa 10 mg filmomhulde tabletten
Qerrassa 15 mg filmomhulde tabletten
Qerrassa 20 mg filmomhulde tabletten

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

1. What Qerrassa is and what it is used for

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

This medicine 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 Qerrassa

Do not take Qerrassa:
- 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 Qerrassa:
- 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 Qerrassa 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.
- if you 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.
- if you have had mania
- if you have a tendency to bleed or bruise easily, or if you are pregnant (See ‘Pregnancy, breast-feeding and fertility’).
- if you have low sodium level in the blood.
- if you are 65 years of age or older.
- if you have a severe kidney disease.
- if you have a severe liver disease or a liver disease called cirrhosis.
- if you 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
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 Qerrassa
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 Qerrassa. If you have taken any of these medicines, you will need to wait 14 days before you start taking Qerrassa. After stopping Qerrassa 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).
- medicines 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 Qerrassa 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.

Drug tests
If you are having a urine drug screen, taking Qerrassa 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.

Qerrassa 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
This medicine should not be used during pregnancy unless the doctor says it is absolutely necessary.

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

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

Driving and using machines
This medicine 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 Qerrassa treatment or changing the dose.

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

3. How to take Qerrassa

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 Qerrassa 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.

Use in elderly patients
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.
If you are not able to swallow the tablet whole, other medicines containing vortioxetine in other pharmaceutical forms may be available on the market.

Duration of treatment
Take this medicine for as long as your doctor recommends.

Continue to take this medicine 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 Qerrassa than you should
If you take more than the prescribed dose of Qerrassa, 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 Qerrassa
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 Qerrassa
Do not stop taking Qerrassa 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 this medicine.

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)

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)

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

5. How to store Qerrassa

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister 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 protect the environment.

6. Contents of the pack and other information

What Qerrassa contains
Qerrassa 5 mg filmomhulde tabletten
- The active substance is vortioxetine. Each film-coated tablet contains 5 mg vortioxetine (as vortioxetine hydrobromide).
- The other ingredients are: mannitol (E421), cellulose microcrystalline, hydroxypropylcellulose, sodium starch glycolate and magnesium stearate in the tablet core, and hypromellose, macrogol, titanium dioxide (E171) and iron oxide red (E172) in the tablet coating.

Qerrassa 10 mg filmomhulde tabletten
- The active substance is vortioxetine. Each film-coated tablet contains 10 mg vortioxetine (as vortioxetine hydrobromide).
- The other ingredients are: mannitol (E421), cellulose microcrystalline, hydroxypropylcellulose, sodium starch glycolate and magnesium stearate in the tablet core, and hypromellose, macrogol, titanium dioxide (E171) and iron oxide yellow (E172) in the tablet coating.

Qerrassa 15 mg filmomhulde tabletten
- The active substance is vortioxetine. Each film-coated tablet contains 15 mg vortioxetine (as vortioxetine hydrobromide).

- The other ingredients are: mannitol (E421), cellulose microcrystalline, hydroxypropylcellulose, sodium starch glycolate and magnesium stearate in the tablet core, and hypromellose, macrogol, titanium dioxide (E171), iron oxide red (E172) and iron oxide yellow (E172) in the tablet coating.

Qerrassa 20 mg filmomhulde tabletten
- The active substance is vortioxetine. Each film-coated tablet contains 20 mg vortioxetine (as vortioxetine hydrobromide).
- The other ingredients are: mannitol (E421), cellulose microcrystalline, hydroxypropylcellulose, sodium starch glycolate and magnesium stearate in the tablet core, and hypromellose, macrogol, titanium dioxide (E171) and iron oxide red (E172) in the tablet coating.

What Qerrassa looks like and contents of the pack
Qerrassa 5 mg filmomhulde tabletten
Pink, oval (11 mm x 5 mm), biconvex film-coated tablet debossed with '5' on one side.

Qerrassa 10 mg filmomhulde tabletten
Yellow, oval (13 mm x 6 mm), biconvex film-coated tablet debossed with '10' on one side.

Qerrassa 15 mg filmomhulde tabletten
Pale orange, oval (15 mm x 7 mm), biconvex film-coated tablet debossed with '15' on one side.

Qerrassa 20 mg filmomhulde tabletten
Dark red, oval (17 mm x 8 mm), biconvex film-coated tablet debossed with '20' on one side.

Qerrassa film-coated tablets are available in carton boxes containing PVC/PVdC//Alu blisters.

Pack sizes of 14, 28 or 56 film-coated tablets

Not all pack sizes may be marketed.

Dit middel is ingeschreven in het register onder nummer:
RVG 130242
RVG 130243
RVG 130244
RVG 130245

Marketing Authorisation Holder and Manufacturer

*Registratiehouder:*Adalvo Competence Centre S.R.L.
47 Theodor Pallady Blvd, Office no 1, entrance B,
1st floor, 3rd District, Bucharest,
Roemenië.

*Fabrikanten:*Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola PLA 3000, Malta.

Adalvo Limited
Malta Life Sciences Park,
Building 1, Level 4, Sir Temi Zammit Buildings,
San Gwann, SGN 3000 Malta

This medicine is authorised in the Member States of the European Economic Area under the following names:

Nederland:	Qerrassa 5mg filmomhulde tabletten Qerrassa 10mg filmomhulde tabletten Qerrassa 15mg filmomhulde tabletten Qerrassa 20mg filmomhulde tabletten
Slovenië:	Qerrassa 5mg filmsko obložene tablete Qerrassa 10mg filmsko obložene tablete Qerrassa 15mg filmsko obložene tablete Qerrassa 20mg filmsko obložene tablete

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.