Package leaflet: Information for the user

Reagila® 3 mg hard capsules

(cariprazine)

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. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Reagila 3 mg hard capsules but will be referred to as Reagila throughout the remainder of the leaflet. Reagila is also available in 1.5 mg, 4.5 mg and 6 mg strength which may be mentioned in this leaflet.

What is in this leaflet

1. What Reagila is and what it is used for

Reagila contains the active substance cariprazine and belongs to a group of medicines called antipsychotics. It is used to treat adults with schizophrenia.
Schizophrenia is a disease characterised by symptoms such as hearing, seeing or sensing things which are not there (hallucination), suspiciousness, mistaken beliefs, incoherent speech and behaviour and emotional flatness. People with this condition may also feel depressed, guilty, anxious, tense, or not being able to start or keep up planned activities, unwillingness to speak, lack of emotional response to a situation that would normally stimulate feelings in others.

2. What you need to know before you take Reagila

Do not take Reagila
- if you are allergic to cariprazine or any of the other ingredients of this medicine (listed in section 6).
- if you are taking medicines used to treat:
  - hepatitis caused by the hepatitis C virus (medicines containing boceprevir and telaprevir)
  - bacterial infections (medicines containing clarithromycin, telithromycin, erythromycin and nafcillin)
  - tuberculosis (medicines containing rifampicin)
  - HIV infections (medicines containing cobicistat, indinavir, nelfinavir, ritonavir, saquinavir, efavirenz and etravirine)
  - fungal infections (medicines containing itraconazole, posaconazole, voriconazole and fluconazole)
  - Cushing's syndrome - when the body produces an excess of cortisol (medicines containing ketoconazole)
  - depression (herbal therapy containing St. John's wort (Hypericum perforatum) and medicines containing nefazodone)
  - epilepsy and seizures (medicines containing carbamazepine, phenobarbital and phenytoin)
  - heart disease (medicines containing diltiazem and verapamil)
  - sleepiness (medicines containing modafinil)
  - high blood pressure in the lungs (medicines containing bosentan).

Warnings and precautions
Tell your doctor immediately:
- if you are having any thoughts or feelings about harming yourself or to commit suicide. Suicidal thoughts and behaviours are more likely at the beginning of the treatment.
- if you experience a combination of fever, sweating, faster breathing, muscle stiffness and drowsiness or sleepiness (may be signs of neuroleptic malignant syndrome).

Talk to your doctor or pharmacist before taking Reagila, or during treatment if you have:
- ever experienced or start to experience restlessness and inability to sit still. These symptoms may occur early during treatment with Reagila. Tell your doctor if this happens.
- ever experienced or start to experience abnormal, involuntary movements, most commonly of the tongue or face. Tell your doctor if this happens.
- visual impairment. Your doctor will advise you to visit an ophthalmologist.
- irregular heartbeat or if someone else in your family has a history of irregular heartbeat (including so called QT prolongation seen with ECG monitoring), and tell your doctor if you are taking other medicines, because they might cause or worsen this ECG change.
- high or low blood pressure, cardiovascular disease. Your doctor will need to check your blood pressure regularly.
- dizziness on standing up due to a drop in your blood pressure, which may cause fainting.
- a history of blood clots, or if someone else in your family has a history of blood clots, as medicines for schizophrenia have been associated with formation of blood clots.
- a history of stroke, especially if you are elderly or know that you have other risk factors for stroke. Tell your doctor immediately if you notice any signs of a stroke.
- dementia (loss of memory and other mental abilities) especially if you are elderly.
- Parkinson's disease.
- if you have diabetes or risk factors for diabetes (e.g. obesity, or someone else in your family has diabetes). Your doctor will need to check your blood sugar regularly since it may be increased by Reagila. Signs of high blood sugar level are excessive thirst, passing of large amounts of urine, increase in appetite and feeling weak.
- a history of seizures (fits) or epilepsy.

Weight increase
Reagila may cause significant weight increase which may affect your health. Your doctor will therefore check your weight regularly.

Children and adolescents
This medicine is not recommended for children and adolescents under 18 years due to the lack of data in these patients.

Other medicines and Reagila
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You cannot take certain medicines together with Reagila (see section "Do not take Reagila").

Taking Reagila together with some medicines may require a dose adjustment of Reagila or the other medicine. These are medicines used to treat heart diseases containing digoxin, blood thinners containing dabigatran, or medicines affecting your mental functions.

Reagila with food, drink and alcohol
You should not drink grapefruit juice during treatment with Reagila.
Alcohol should be avoided when taking Reagila.

Pregnancy and breast-feeding

Women of childbearing potential/Contraception
Women of childbearing potential must use effective contraception during Reagila treatment. Even after treatment is stopped, contraception must be used for at least 10 weeks after your last dose of Reagila. This is because the medicine will stay in your body for some time after the last dose was taken.

Pregnancy
Do not take this medicine during pregnancy unless your doctor has told you to do so.

If your doctor decides that you should take this medicine during pregnancy, your doctor will monitor your baby closely after birth. This is because the following symptoms may occur in newborn babies of mothers who have used this medicine in the last trimester (last three months) of their pregnancy:
- shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding.

If your baby develops any of these symptoms you should contact your doctor.

Breast-feeding
Do not breast-feed if you are taking Reagila because a risk for the baby cannot be excluded. Contact your doctor for advice.

Driving and using machines
There is a minor or moderate risk that the medicine could affect the ability to drive and use machines. Drowsiness, dizziness and vision problems may occur during treatment with this medicine (see section 4). Do not drive or use any tools or machines until you know that this medicine does not affect you in a negative way.

Reagila 3 mg, 4.5 mg, 6 mg hard capsules contain Allura red AC (E 129).
Allura red AC is a coloring agent, which may cause allergic reactions.

3. How to take Reagila

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

The recommended starting dose is 1.5 mg once a day by mouth. Thereafter, the dose may be slowly adjusted by your doctor, in steps of 1.5 mg, depending on how the treatment works for you.
The maximum dose should not exceed 6 mg once a day.
Take Reagila at the same time each day with or without food.
If you were taking another medicine to treat schizophrenia before starting Reagila, your doctor will decide whether to stop the other medicine gradually or immediately and how to adjust the dose of Reagila. Your doctor will also inform you how to act if you switch from Reagila to another medicine.

Patients with kidney or liver problems
If you have serious kidney or liver problems Reagila may not be appropriate for you. Talk to your doctor.

Elderly patients
Your doctor will carefully select the appropriate dose for your needs.
Reagila should not be used by elderly patients with dementia (loss of memory).

If you take more Reagila than you should
If you have taken more Reagila than your doctor has recommended or if, for example, a child has taken it by mistake, contact your doctor or go to the nearest hospital right away and take the pack of the medicine with you. You may experience dizziness from low blood pressure, or have abnormal heartbeats, you may feel sleepy, tired, or have abnormal body movements and find it difficult to stand or walk.

If you forget to take Reagila
If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual.
Do not take a double dose to make up for a forgotten dose.
If you miss two or more doses, contact your doctor.

If you stop taking Reagila
If you stop taking this medicine you will lose the effects of the medicine. Even if you feel better, do not alter or stop your daily dose of Reagila unless told to do so by your doctor as your symptoms may return.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

Tell your doctor **immediately** if you have:
- a severe allergic reaction seen as fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash and sometimes a drop in blood pressure. *(Rare side effect)*
- combination of fever, sweating, muscle stiffness, and drowsiness or sleepiness. These can be the signs of the so-called neuroleptic malignant syndrome. *(Side effect with frequency not known)*
- inexplicable muscle pains, muscle cramps or muscle weakness. These may be signs of muscle damage which can cause very serious kidney problems. *(Rare side effect)*

- symptoms related to blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
  (Side effect with frequency not known)
- thoughts or feelings about harming yourself or to commit suicide, suicide attempt.
  (Uncommon side effect)

Other side effects

Very common side effects (may affect more than 1 in 10 people)

- feeling of restlessness and inability to sit still
- Parkinsonism - a medical condition with many various symptoms which include decreased or slow movements, slowness of thought, jerks when bending the limbs (cogwheel rigidity), shuffling, steps, shaking, little or no facial expression, muscle stiffness, drooling

Common side effects (may affect up to 1 in 10 people)

- anxiety
- sleepiness, difficulty in sleeping, abnormal dreams, nightmare, sleepwalking
- dizziness
- involuntary twisting movements and strange postures
- excessive teeth grinding or jaw clenching, drooling, persistent blinking in response to tapping of the forehead (an abnormal reflex), movement problems, tongue movement disturbance (these are called extrapyramidal symptoms)
- blurred vision
- high blood pressure
- fast, irregular heartbeat
- decreased or increased appetite
- nausea, vomiting, constipation
- weight increased
- tiredness
- the following can be seen in laboratory tests:
  - increases in liver enzymes
  - increases in the level of creatine phosphokinase in the blood
  - abnormal amount of lipids (e.g. cholesterol and/or fat) in the blood

Uncommon side effects (may affect up to 1 in 100 people)

- depression
- sudden and severe confusion
- spinning sensation
- unpleasant, abnormal sense of touch
- drowsiness, lack of energy or a lack of interest in doing things
- involuntary movements, most commonly of the tongue or face. This can appear after short or long-term use.
- decreased or increased sexual desire, erectile problems
- eye irritation, high pressure in the eye, poor vision
- focusing problems seeing at a distance to or seeing close-to
- low blood pressure
- abnormal ECG reading, abnormal nerve impulses in the heart
- slow, irregular heart rate
- hiccups
- heartburn
- thirst
- pain when passing urine
- abnormally frequent and large urinations
- itching, rash
- diabetes
- the following can be seen in laboratory tests:
  - abnormal sodium level in the blood
  - increased blood glucose (blood sugar), increased bile pigment (bilirubin) in the blood
  - anaemia (reduced levels of red blood cells)
  - increase in a type of white blood cells
  - decreased level of thyroid stimulating hormone (TSH) in the blood

Rare side effects (may affect up to 1 in 1,000 people)

- seizure
- loss of memory, loss of speech
- eye discomfort in bright light
- clouding of the lens in the eye leading to a decrease in vision (cataract)
- difficulty in swallowing
- reduced levels of a type of white blood cells, this can make you more susceptible to infections
- underactive thyroid gland

Side effects with not known frequency (frequency cannot be estimated from the available data)

- inflammation of the liver (pain in the upper right abdomen, yellowing of the eye and skin, weakness, fever)

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 at: 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 Reagila

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after "EXP". The expiry date refers to the last day of that month.

Keep the blister in the outer carton in order to protect from light.
This medicine does not require any special temperature storage conditions.

If your medicine shows any signs of deterioration or discolouration, consult your pharmacist for advice.
If damaged, please tell your doctor or pharmacist.

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

6. Contents of the pack and other information

What Reagila contains

- The active substance is cariprazine.
  Each hard capsule contains cariprazine hydrochloride corresponding to 3 mg cariprazine.

- The other ingredients are:
  Pregelatinized (maize) starch, magnesium stearate, allura red AC (E 129), brilliant blue FCF (E 133), titanium dioxide (E 171), yellow iron oxide (E 172), gelatin, black ink (shellac, black iron oxide (E 172), propylene glycol, potassium hydroxide).

What Reagila looks like and contents of the pack

'Size 4' (approximately 14.3 mm in length) hard gelatin capsule with green opaque cap and white opaque body imprinted with "GR 3" on the capsule body with black ink. The capsules are filled with white to yellowish white powder.

The capsules are packed in transparent hard PVC/ PE/PVDC blister heat-sealed with hard aluminium foil backing.

Reagila 3 mg are available in blister packs containing 28 hard capsules.

PLGB 20774/2545 Reagila 3 mg hard capsules **POM**

Manufactured by: Gedeon Richter Plc., Gyömrői út 19-21., 1103 Budapest, Hungary. Procured from within the EU. Product Licence Holder: Quadrant Pharmaceuticals Limited, Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA. Repackaged by: Maxearn Limited, Unit 29, Oakhill Trading Estate, Devonshire Rd, Worsley, Manchester, M28 3PT.

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Blind or partially sighted?
Is this leaflet hard to see or read?
Contact Quadrant Pharmaceuticals Ltd., Tel: 01204 471 269

For any information about this medicine, please contact the Product Licence Holder: Quadrant Pharmaceuticals Limited on 01204 471269.