

Package leaflet: Information for the user

Ridonex 10 mg Orodispersible Tablets

Domperidone

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

1. What Ridonex is and what it is used for

This medicine contains domperidone, which is a dopamine antagonist. It acts as a gastric motility agent. This medicine is used to treat nausea (feeling sick) and vomiting (being sick) in adults and adolescents (12 years of age and older and weighing 35 kg or more).

2. What you need to know before you take Ridonex

DO NOT take Ridonex if you:

- are allergic to domperidone or any of the other ingredients of this medicine (listed in section 6)
- have stomach bleeding or if you regularly have severe abdominal pain or persistent black stools (poo)
- have a blocked or perforated gut
- have a tumour of the pituitary gland (prolactinoma)
- have a moderate or severe liver disease
- have an ECG (electrocardiogram) that shows a heart problem called “prolonged QT interval”
- have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure)
- have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood
- are taking certain medicines (see “Other medicines and Ridonex”)

Warnings and precautions

Talk to your doctor or pharmacist before taking Ridonex if you:

- suffer from liver problems (liver function impairment or failure) (see “Do not take Ridonex”)
- suffer from kidney problems (kidney function impairment or failure). It is advisable to ask your doctor for advice in case of prolonged treatment as you may need to take a lower dose or take this medicine less often, and your doctor may want to examine you regularly.

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or in those taking doses higher than 30 mg per day. The risk also increases when domperidone is given together with some drugs. Tell your doctor or pharmacist if you are taking drugs to treat infection (fungal infections or bacterial infection) and/or if you have heart problems or AIDS/HIV (see “Other medicines and Ridonex”).

Domperidone should be used at the lowest effective dose.

While taking Ridonex, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, loss of consciousness. Treatment with Ridonex should be stopped.

Adolescents weighing less than 35 kg and children

Ridonex should not be given to adolescents 12 years of age and older, weighing less than 35 kg, or any children less than 12 years of age, as it is not effective in these age groups.

Other medicines and Ridonex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Ridonex if you are taking medicine to treat:

- fungal infections, e.g., pentamide or azole anti-fungals, specifically itraconazole, oral ketoconazole, fluconazole, posaconazole or voriconazole
- bacterial infections, specifically erythromycin, clarithromycin, telithromycin, levofloxacin, moxifloxacin, spiramycin (these are antibiotics)
- heart problems or high blood pressure (e.g., amiodarone, dronedarone, ibutilide, disopyramide, dofetilide, sotalol, hydroquinidine, quinidine)
- psychoses (e.g., haloperidol, pimozide, sertindole)
- depression (e.g., citalopram, escitalopram)
- gastrointestinal disorders (e.g., cisapride, dolasetron, prucalopride)
- allergy (e.g., mequitazine, mizolastine)
- malaria (in particular halofantrine, lumefantrine)
- AIDS/HIV such as ritonavir or saquinavir (these are protease inhibitors)
- hepatitis C (e.g., telaprevir)
- cancer (e.g., toremifene, vandetanib, vincamine)

Do not take Ridonex if you are taking certain other medicines (e.g. bepridil, diphemanil, methadone).

Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems, AIDS/HIV or Parkinson's disease.

Ridonex and apomorphine

Before you use Ridonex and apomorphine, your doctor will ensure that you tolerate both medicines when used simultaneously. Ask your doctor or specialist for a personalised advice. Please refer to the apomorphine leaflet.

It is important to ask your doctor or pharmacist if Ridonex is safe for you when you are taking any other medicines, including medicines obtained without prescription.

Ridonex with food

Take Ridonex before meals, as when taken after meals, the absorption of the medicine is slightly delayed.

Pregnancy

It is not known whether the use of Ridonex is harmful during pregnancy.

If you are pregnant or think you may be you should inform your doctor who will decide if you can take Ridonex.

Breast-feeding

Small amounts of domperidone have been detected in breast milk. Domperidone may cause unwanted side effects affecting the heart in a breast-fed baby. Ridonex should be used during breast-feeding only if your doctor considers this clearly necessary. Ask your doctor for advice before taking this medicine.

Driving and using machines

Some patients have reported feeling dizzy or sleepy after taking domperidone. Do not drive or use machinery while taking Ridonex until you know how Ridonex affects you.

Ridonex contains sulphur dioxide (E220), sodium and maltodextrin

Sulphur dioxide (E220) may rarely cause severe hypersensitivity reactions and bronchospasm.

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

The excipient maltodextrin contains source of glucose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

3. How to take Ridonex

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

Posology**Adults and adolescents 12 years of age and older with a body weight of 35 kg or more**

The usual dose is one tablet taken up to three times per day, if possible before meals. Do not take more than three tablets per day.

Domperidone is not to be used in children under 12 years and in adolescents weighing less than 35 kg.

Orodispersible tablet are fragile. They must be pushed carefully through the packaging (blister) to avoid damage.

Duration of treatment

Symptoms usually resolve with 3-4 days of taking this medicine. Do not take Ridonex for longer than 7 days without consulting your doctor.

Method of administration

Oral route.

The orodispersible tablet dissolves rapidly in the mouth in the saliva, and can be taken without water. Generally speaking, let the tablet dissolve in the mouth without chewing. Patients may drink a glass of water after taking the tablet if necessary.

Take Ridonex before meals, as when taken after meals, the absorption of the medicine is slightly delayed.

If you take more Ridonex than you should

If you have used or taken too much Ridonex, contact your doctor, pharmacist or the poison centre immediately. In the event of overdose, symptomatic treatment could be implemented. An ECG monitoring could be undertaken, because of the possibility of a heart problem called "prolonged QT interval".

Information for the doctor: close observation of the patient and general supportive measures are recommended. Anticholinergic anti-Parkinson medication may help to counteract the extrapyramidal disorders.

If you forget to take Ridonex

Take your medicine as soon as you remember. If it is almost time for your next dose, wait until that is due and then continue as normal. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

Stop treatment with Ridonex and contact your doctor immediately if you experience any of the unwanted events:

Uncommon (may affect up to 1 in 100 people):

- involuntary movements of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasm

Not known (frequency cannot be estimated from the available data):

- seizures
- a type of reaction that may occur soon after administration and is recognised by skin rash, itching, shortness of breath, and/or a swollen face
- a severe hypersensitivity reaction that may occur soon after administration that is characterised by hives, itching, flushing, fainting, and difficulty breathing among other possible symptoms
- disorders of the cardiovascular system: heart rhythm disorders (rapid or irregular heart beat) have been reported; if this happens, you should stop the treatment immediately. Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day. Domperidone should be used at the lowest effective dose

Other unwanted effects that have been observed with domperidone are listed below:

Common (may affect up to 1 in 10 people)

- dry mouth

Uncommon (may affect up to 1 in 100 people)

- anxiety
- agitation
- nervousness
- loss of interest in sex or diminished interest in sex
- headache
- sleepiness
- diarrhoea
- rash
- itchiness
- hives
- painful or tender breasts
- milk discharge from breasts
- a general feeling of weakness
- feeling dizzy

Not known (frequency cannot be estimated from the available data)

- upward moving of the eyes
- stopped menstrual periods in women
- enlarged breasts in men
- inability to urinate
- changes in certain laboratory test results
- restless legs syndrome (uncomfortable feeling, with an irresistible urge to move your legs, and sometimes arms and other parts of your body)

Some patients who have used domperidone for conditions and dosages requiring medical oversight have experienced the following unwanted effects:

Restlessness; swollen or enlarged breasts, unusual discharge from breasts, irregular menstrual periods in women, difficulty breast-feeding, depression, hypersensitivity.

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:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ridonex

Do not store above 30 °C. Store in the original package in order to protect from moisture.

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 label and carton after EXP. The expiry date refers to the last day of that month.

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 Ridonex contains

- *The active substance is domperidone.*
Each orodispersible tablet contains 10 mg of domperidone.
- *The other ingredients are:*
Microcrystalline cellulose, crospovidone, lemon flavouring*, magnesium stearate, sodium saccharin, sodium laurylsulfate, hydrophobic colloidal silica
*Lemon flavouring: maltodextrin (source of glucose), gum acacia, butylated hydroxyanisole, sulphurous anhydride (E220), alpha-pinene, beta-pinene, myrcene, limonene, gamma-terpinene, neral and geranial.

What Ridonex looks like and contents of the pack.

Ridonex is a white tablet round with 5 mm of diameter available in packs containing 10, 20 and 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

DELPHARM EVREUX, 5 rue du Guesclin, 27000 EVREUX, France
STADA Arzneimittel AG, Stadastrasse 2 – 18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Domperidone STADA 10 mg Comprimé orodispersible
Croatia	Domperidon STADA 10 mg raspadljive tablete za usta
Ireland	Ridonex 10 mg orodispersible tablets

This leaflet was last revised in April 2021.