Package leaflet: Information for the user

Ridecia 0.5 mg film-coated tablets
Ridecia 1 mg film-coated tablets
Ridecia 1.5 mg film-coated tablets
Ridecia 2 mg film-coated tablets
Ridecia 2.5 mg film-coated tablets

riociguat

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.
- This leaflet has been written as though the person taking the medicine is reading it. If you are giving this medicine to your child, please replace "you" with "the child" throughout.

What is in this leaflet

1. What <Invented name> is and what it is used for

<Invented Name> contains the active substance riociguat, a guanylate cyclase (sGC)-stimulator.

It is used to treat adults and children from 6 years of age with certain types of pulmonary hypertension:
- **Chronic thromboembolic pulmonary hypertension (CTEPH).**
  <Invented Name> is used to treat adult patients with CTEPH. In patients with CTEPH, the blood vessels of the lung are blocked or narrowed by blood clots. The medicine can be used in patients with CTEPH who cannot be operated on, or in patients in whom pulmonary hypertension remains or returns after surgery.
- **Pulmonary arterial hypertension (PAH).**
  <Invented Name> is used to treat adults and children aged 6 years or older with pulmonary arterial hypertension. In these patients, the walls of the blood vessels of the lungs are thickened and the vessels become narrowed. In patients with PAH, <Invented Name> is taken together with certain other medicines (so-called endothelin receptor antagonists). In adults, the medicine can also be taken on its own (monotherapy).

In patients with pulmonary hypertension, the blood vessels that carry blood from the heart to the lungs become narrowed, making it harder for the heart to pump blood to the lungs, and leading to high blood pressure in the vessels. Because the heart must work harder than normal, people with pulmonary hypertension feel tired, dizzy and short of breath. <Invented Name> widens the blood vessels that lead from the heart to the lungs, reducing symptoms of the disease and better allowing patients to carry out physical activity better.

2. What you need to know before you take <Invented Name>

Do not take <Invented Name> if you

- take **PDE5 inhibitors** such as sildenafil, tadalafil, vardenafil. These are medicines to treat high blood pressure in lung arteries or erectile dysfunction.
- have **severely reduced liver function.**
- are **allergic** to riociguat or any of the other ingredients of this medicine (listed in section 6).
- are **pregnant.**
- take **nitrates** or **nitric oxide donors** such as amyl nitrite. These are medicines often used to treat high blood pressure, chest pain or heart disease. This also includes recreational drugs called poppers.
- take other medicines, similar to <Invented Name> called **soluble guanylate cyclase stimulators**, such as vericiguat. Ask your doctor if you are not sure.
- have **low blood pressure** before you take <Invented Name> the first time. To start with <Invented Name> your systolic blood value should be
  - 90 mmHg or more if your age is between 6 and 12 years,
  - 95 mmHg or more if you are 12 years old or older.
- have **increased blood pressure** in your lungs associated with scarring of the lungs, of unknown cause called idiopathic pulmonary pneumonia.

If any of these apply to you, **talk to your doctor first** and do not take <Invented Name>.

Warnings and precautions

Talk to your doctor or pharmacist before taking <Invented Name> if you

- have **pulmonary veno-occlusive disease**, a disease which makes you **feel short of breath** because fluid builds-up in the lungs. He or she may decide to provide you with an alternative medicine.
- have recently had serious **bleeding from the lung**s and airways.
- have undergone treatment to stop **coughing up blood** (bronchial arterial embolisation).
- take medicines that prevent the blood from clotting since this may cause bleeding from the lungs. Your doctor will regularly test your blood and measure blood pressure.
- The doctor may decide to monitor the blood pressure, if you
  - have symptoms of **low blood pressure** like dizziness, lightheadedness, or fainting or i
  - take medicines to lower blood pressure or to increase urination, or
  - have **heart or circulation problems**
  - are older than 65 years as low blood pressure is more likely in this age group.

Inform your doctor if

- you are **on dialysis** or if the **kidneys do not work properly**, as use of this medicine is not recommended.
- your **liver does not work properly**.

While using <Invented Name>, talk to your doctor if you

- feel **short of breath** during treatment with this medicine. This can be caused by a build-up of fluid in the lungs. If this is due to pulmonary veno-occlusive disease your doctor may stop treatment with <Invented Name>.
- start or stop **smoking** during treatment with this medicine, because this may influence the level of riociguat in your blood.

Children and adolescents

- **Chronic thromboembolic pulmonary hypertension (CTEPH)**
  - <Invented Name> is not recommended for use in CTEPH patients less than 18 years of age.
- **Pulmonary arterial hypertension (PAH)**
  - You have been prescribed <Invented Name> tablets. For PAH patients of 6 years and older that weigh less than 50 kg, riociguat in other pharmaceutical forms is available.

Patients may switch between pharmaceutical forms during therapy due to body weight changes**.**

Efficacy and safety have not been shown in the following paediatric populations:

- Children less than 6 years because of safety concerns.

Other medicines and <Invented Name>

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

- **Do not take medicines used for**
  - high blood pressure or heart disease such as **nitrates and amyl nitrite,** or another **soluble guanylate cyclase stimulato**rs such as **vericiguat**. Do not take these medicines together with <Invented Name>.
  - high blood pressure in lung arteries, as you must not take certain medicines such as **sildenafil**, **tadalafil** together with <Invented Name>. Other medicines for high blood pressure in the lung arteries, such as **bosentan** and **iloprost**, can be used with <Invented Name>, but you should inform the doctor.
  - erectile dysfunction such as **sildenafil, tadalafil, vardenafil**. Do not take these medicines together with <Invented Name>.
- **The following medicines can increase the level of <Invented Name> in the blood which increases the risk of side effects**
  - fungal infections such as **ketoconazole, posaconazole, itraconazole**
  - HIV infection such as **abacavir, atazanavir, cobicistat, darunavir, dolutegravir, efavirenz, elvitegravir, emtricitabine, rilpivirine, ritonavir.**
  - epilepsy such as **phenytoin, carbamazepine, phenobarbitone**.
  - depression such as **St. John's Wort**.
  - preventing rejection of transplanted organs such as **ciclosporin**.
  - cancer such as **erlotinib, gefitinib**.
  - nausea, vomiting such as **granisetron**.
  - to treat stomach disease or heartburn called **antacids** such as **aluminium hydroxide / magnesium hydroxide used**. Take antacids at least 2 hours before or 1 hour after using <Invented Name>.

<Invented Name> with food

<Invented Name> can generally be taken with or without food.

However, if your blood pressure tends to be low, take <Invented Name> either always with food or always without food.

Pregnancy and breast-feeding

- **Birth control:** Women and female adolescents of childbearing potential must use effective contraception during treatment with <Invented Name>. Talk to your doctor about suitable methods of contraception you may use to prevent pregnancy. In addition, you should take monthly pregnancy tests.
- **Pregnancy:** Do not use <Invented Name> during pregnancy.
- **Breast-feeding:** Breast-feeding is not recommended while using this medicine because it might harm the baby. Inform your doctor if you are currently breast-feeding, or planning to breast-feed before using this medicine. Your doctor will decide with you to either stop breast-feeding or to stop using <Invented Name>.

Driving and using machines

<Invented Name> moderately influences the ability to cycle, drive and use machines. It may cause side effects such as dizziness. You should be aware of the side effects of this medicine before cycling, driving or using machines (see section 4).

<Invented Name> contains lactose

If you have been told by a doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

<Invented Name> 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 <Invented Name>

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

<Invented Name> is available as a tablet.

The tablets are available for use by adults and children weighing at least 50 kg. Riociguat is available also for children weighing less than 50 kg in other pharmaceutical forms.

Treatment should only be started by a doctor experienced in the treatment of high blood pressure in lung arteries, who will monitor you during treatment. During the first weeks of treatment your doctor will need to measure your blood pressure at regular intervals. <Invented Name> is available in different strengths and by checking your blood pressure regularly at the beginning of your treatment, your doctor will ensure that you are taking the appropriate dose.

How to start treatment:
Your doctor will tell you what dose of <Invented Name> to take.
- Treatment usually starts with a low dose.
- Your doctor will slowly increase your dose depending on how you respond to the treatment.
- During the first weeks of treatment the doctor will need to measure your blood pressure at least every two weeks. This is required to decide on the correct dose of your medicine.

How to take the medicine
<Invented Name> is for oral use. The tablets should be taken 3 times a day, every 6 to 8 hours.

Crushed tablets:
If you have difficulty swallowing the whole tablet, talk to your doctor about other ways to take <Invented Name>. The tablet may be crushed and mixed with water or a soft food, immediately before you take it.

How much you have to take
The recommended starting dose is a 1 mg tablet taken 3 times a day for 2 weeks.
Your doctor will increase the dose every 2 weeks to a maximum of 2.5 mg 3 times a day (maximum daily dose of 7.5 mg) unless you experience very low blood pressure. In this case, your doctor will prescribe you <Invented Name> at the highest dose you are comfortable on. The best dose will be selected by your doctor. For some patients' lower doses 3 times a day might be sufficient.

If you are 65 years or older
You may be at greater risk of low blood pressure. Your doctor may adjust the dose.

If you smoke
If you smoke, it is recommended that you stop before starting treatment, as smoking may reduce the effectiveness of these tablets. Please tell your doctor if you smoke or stop smoke during treatment. Your doctor may need to adjust your dose.

If you take more <Invented Name> than you should
Please contact the doctor if you took more <Invented Name> than you should and if you notice any side effects (see section 4). If your blood pressure drops (which can make you feel dizzy) then you may need immediate medical attention.

If you forget to take <Invented Name>
Do not take a double dose to make up for a forgotten dose. If you miss a dose, continue with the next dose as planned.

If you stop taking <Invented Name>
Do not stop taking this medicine without talking to your doctor first. If you stop to taking this medicine, your disease may worsen. If you have not taken this medicine for 3 days or more, please tell your doctor before you start taking it again.

If you are switching between <Invented Name> and sildenafil or tadalafil
To avoid interactions, <Invented Name> and PDE5 inhibitors (sildenafil, tadalafil) must not be taken at the same time.
- If you switch to <Invented Name>
  - do not start <Invented Name> for at least 24 hours after your last dose of sildenafil and at least 48 hours after your last dose of tadalafil.
- If you switch from <Invented Name>
  - stop using <Invented Name> at least 24 hours before you start using sildenafil or tadalafil.

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.

The most **serious** side effects **in adults** are:
- **coughing up blood** (haemoptysis) (common, may affect up to 1 in 10 people),
- **acute bleeding from the lungs** (pulmonary haemorrhage) which may result in coughing up blood and can be fatal (uncommon, may affect up to 1 in 100 people).

If this happens, **contact your doctor immediately** as you may need urgent medical treatment.

Overall list of possible side effects (in adult patients)

Very common: may affect more than 1 in 10 people
- dizziness
- headache
- indigestion (dyspepsia)
- diarrhoea
- feeling sick (nausea)
- vomiting
- swelling of limbs (oedema peripheral)

Common: may affect up to 1 in 10 people
- inflammation in the digestive system (gastroenteritis)
- low levels of red blood cells (anaemia). Symptoms are pale skin, weakness or breathlessness
- irregular, hard or rapid heartbeat (palpitations)
- low blood pressure (hypotension)
- nose bleed (epistaxis)
- difficulty breathing through your nose (nasal congestion)
- inflammation of the stomach (gastritis)
- heartburn (gastro-oesophageal reflux disease)
- difficulty in swallowing (dysphagia)
- pain in the stomach, intestine or abdomen (gastrointestinal and abdominal pain)
- constipation
- bloating (abdominal distension)

Side effects in children
In general, side effects observed in **children aged 6 to less than 18 years** treated with <Invented Name> were similar to those observed in adults. The most **frequent** side effects **in children** were:
- **low blood pressure** (hypotension) (**Very common:** may affect more than 1 in 10 people)
- **headache** (Common: may affect up to 1 in 10 people)

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 <Invented Name>

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister 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 <Invented Name> contains

- **The active substance** is riociguat.
  <Invented Name> 0.5 mg film-coated tablets
  Each film-coated tablet contains 0.5 mg riociguat.
  <Invented Name> 1 mg film-coated tablets
  Each film-coated tablet contains 1 mg riociguat.
  <Invented Name> 1.5 mg film-coated tablets
  Each film-coated tablet contains 1.5 mg riociguat.
  <Invented Name> 2 mg film-coated tablets
  Each film-coated tablet contains 2 mg riociguat.
  <Invented Name> 2.5 mg film-coated tablets
  Each film-coated tablet contains 2.5 mg riociguat.
- The **other ingredients** are:
  Tablet core: cellulose microcrystalline, lactose monohydrate, hypromellose 2910 (E464), crospovidone (type B), sodium laurilsulfate and magnesium stearate (see end of section 2 for further information on lactose and sodium).
  Tablet-coat: hypromellose 2910 (E464), calcium carbonate (E170), macrogol 400 (E1521)
  <Invented Name> 1 mg, 1.5 mg tablets also contain iron oxide yellow (E 172).
  <Invented Name> 2 mg and 2.5 mg tablets also contain iron oxide yellow (E172) and iron oxide red (E 172).

What <Invented Name> looks like and contents of the pack

<Invented Name> is a film-coated tablet:
<Invented Name> 0.5 mg film-coated tablets
- *0.5 mg tablet:* white, round, biconvex film coated tablet, marked with 0.5 on one side with approximate diameter 5.3 mm.

<Invented Name> 1 mg film-coated tablets
- *1 mg tablet:* pale yellow, round, biconvex film coated tablet, marked with 1 on one side with approximate diameter 7.1 mm.

<Invented Name> 1.5 mg film-coated tablets
- *1.5 mg tablet:* yellow, round, biconvex film coated tablet, marked with 1.5 on one side with approximate diameter 5.6 mm.

<Invented Name> 2 mg film-coated tablets
- *2 mg tablet:* orange, round, biconvex film coated tablet, marked with 2 on one side with approximate diameter 6.1 mm.

<Invented Name> 2.5 mg film-coated tablets
- *2.5 mg tablet:* orange-brown, round, biconvex film coated tablet, marked with 2.5 on one side with approximate diameter 7.1 mm.

<Invented name> is available in:

Plain blisters and calendar blisters. Both types of blisters are intended for all pack sizes.

Pack sizes of 42, 84, 90 and 294 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

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

<{Name of the Member State}> <{Name of the medicine}>
<{Name of the Member State}> <{Name of the medicine}>

This leaflet was last revised in 29 April 2026.

<[To be completed nationally]>