

Rapiscan® 400 microgram solution for injection

(regadenoson)

Var 0004: To combine the PLPI numbers of the different source countries and the approved manufacturers

K511209P99-A2.0

Read all of this leaflet carefully before you are given 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.

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 product is called Rapiscan 400 microgram solution for injection but will be referred to as Rapiscan throughout the leaflet.

What is in this leaflet:

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

1. WHAT RAPISCAN IS AND WHAT IT IS USED FOR

Rapiscan contains the active substance regadenoson. This belongs to a group of medicines called 'coronary vasodilators'. It makes the heart arteries expand and heart rate increase. This makes more blood flow to the muscles of the heart.

This medicine is for diagnostic use only.

Rapiscan is used in a type of heart scan in adults called 'myocardial perfusion imaging'.

The scan uses a diagnostic agent to create images. These images show how well blood flows to the muscles of the heart. Usually, exercise on a treadmill is used to put the heart under stress before a scan. During the exercise, a small amount of the diagnostic agent is injected into the body, often into a vein in the hand. Images are then taken of the heart. The doctor can then see if the heart muscles are getting enough blood flow when it is under stress.

If you are unable to exercise enough to reach sufficient stress to the heart, Rapiscan will be injected to provide a stress of similar amplitude to the heart to increase the blood flow.

Rapiscan is also used during catheterisation and imaging arteries of the heart (invasive coronary angiography) to expand the arteries of the heart to measure the difference in pressure, caused by a narrowing within one or more arteries. During cardiac catheterisation, a long thin tube called a catheter is inserted either through your femoral or radial artery and threaded through your blood vessels to your heart. The doctor performing the catheterisation may also want to measure the difference in pressure (fractional flow reserve) due to a narrowing detected in one or more arteries of the heart.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN RAPISCAN**Do not take Rapiscan:**

- if you have slow heart rate (high degree heart block or sinus node disease), and don't have a pacemaker fitted.
- if you have chest pain that occurs unpredictably (unstable angina) and that has not improved after treatment.
- if you have low blood pressure (hypotension).
- if you have heart failure.
- if you are allergic to regadenoson or any of the other ingredients of Rapiscan listed in section 6 of this leaflet.

Talk to your doctor, or nurse before taking Rapiscan

Your doctor needs to know before you are given Rapiscan:

- if you have had a **recent serious heart problem** (for example a heart attack or abnormal heart rhythms).
- if you have a heart rhythm where your heartbeat is very fast or uneven (atrial fibrillation or atrial flutter)
- if you have high blood pressure that is not controlled, especially if this has been accompanied by recent episodes of nose bleed, headache or blurred or double vision.
- if you have had episodes of mini strokes (called transient ischaemic attacks)
- if you have a heart rhythm disorder called **long QT syndrome**.
- if you have episodes of **heart block** (which can slow the heart down) or a **very slow heart rate**.
- if you have any **heart or blood vessel condition**, particularly one that **gets worse** when your blood pressure decreases. These include low blood volume (caused, for example, by severe diarrhoea or dehydration or taking water pills), inflammation around the heart (pericarditis) and some forms of heart valve or artery disease (for example, aortic or mitral stenosis).

- if you have a condition that causes fits (seizures), such as epilepsy, or if you have ever had fits.
- if you have **asthma or lung disease**.

If any of these apply to you, **tell your doctor before you are given the injection.**

Children and adolescents

Rapiscan should not be used in children and adolescents below the age of 18 years.

Other medicines and Rapiscan

Please tell your doctor if you are taking or have recently taken any other medicines including medicines obtained without prescription.

Particular care should be taken with the following medicines:

- **theophylline**, a medicine used to treat asthma and other lung diseases, **must not be used for at least 12 hours before you are given Rapiscan** because it can block the effect of Rapiscan.
- **dipyridamole**, a medicine used to prevent blood clots, **must not be used for at least two days before you are given Rapiscan** because it can change the effect of Rapiscan.

Rapiscan with food and drink

Do not eat food or have drinks containing caffeine (for example, tea, coffee, cocoa, cola or chocolate) for at least 12 hours before you are given Rapiscan. This is because caffeine can interfere with the effect of Rapiscan.

Pregnancy and breast-feeding

Before you are given Rapiscan, tell your doctor:

- if **you are pregnant**, think you are pregnant or planning to have a baby. There is no adequate information on the use of Rapiscan in pregnant women. Harmful effects have been seen in animal studies but it is not known if there is a risk to humans. Your doctor will only give you Rapiscan if it is clearly necessary.
- if **you are breast-feeding**. It is not known whether Rapiscan can pass into breast milk and will only be given to you if your doctor thinks it is necessary. You should avoid breast-feeding for at least 10 hours after you are given Rapiscan.

Ask your doctor for advice before using any medicine.

Driving and using machines

Rapiscan may make you feel dizzy. It may cause other symptoms (headache or shortness of breath) that could affect your ability to drive or use machinery. These effects usually do not last longer than 30 minutes. Do not drive or operate machinery until these effects have improved.

Rapiscan contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose. After you have been given Rapiscan, you will be given an injection of sodium chloride 9 mg/ml (0.9%) solution which contains 45 mg of sodium. To be taken into consideration if you are on a controlled sodium diet.

3. HOW RAPISCAN IS GIVEN**Rapiscan is injected by a healthcare professional** (a doctor, nurse or medical technician) in a medical facility where your heart and blood pressure can be monitored.

It is injected directly into a vein, as a single dose of 400 micrograms in a 5 ml solution – the injection will take about 10 seconds to complete. The dose injected does not depend on your weight.

You will also be given an injection of sodium chloride 9 mg/ml (0.9%) solution (5 ml), and an injection of a small amount of a diagnostic agent.

When you are given Rapiscan, your heart rate will increase quickly. Your heart rate and blood pressure will be monitored.

After the Rapiscan injection you will need to sit or lie down until your heart rate and blood pressure return to your normal levels. The doctor, nurse or medical technician will let you know when you can stand up.

A scan of your heart will be made after enough time has passed to allow the diagnostic agent to reach the heart muscle.

During catheterisation of the arteries of the heart, your doctor may measure the pressure difference (also known as fractional flow reserve – FFR) due to a narrowing in one or more arteries of the heart.

If deemed necessary, a second dose of 400 micrograms can be injected at least 10 minutes after the first dose for such pressure difference measurement during the same catheterization procedure. Heart rate and blood pressure will be monitored during the entire procedure.

If you are more than 65 years old

Some people over 65 years old may experience dizziness and increased heart rate when they have been given too much Rapiscan. If your doctor thinks that you are having severe side effects, or the effects of Rapiscan are lasting too long, they may give you an injection of a medicine called aminophylline that reduces these effects.

4. POSSIBLE SIDE EFFECTS

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

The side effects are usually mild. They normally start soon after the Rapiscan injection and are **usually over within 30 minutes.** They don't usually need any treatment.

More serious side effects include:

- sudden stopping of the heart or damage to the heart, heart block (a disorder of the heart's electrical signal, where the signal cannot pass from the upper to the lower chambers), rapid heart beat
- low blood pressure which may result in fainting or mini strokes (including weakness of the face or an inability to speak). Rarely, Rapiscan can cause a stroke (also known as a cerebrovascular accident).
- an allergic reaction which can cause rash, wheals/weals, swelling under the skin near the eyes or throat, throat tightness, and difficulty in breathing may occur immediately or have delayed onset after Rapiscan injection

Tell your doctor straight away if you think you are having severe side effects. Your doctor may then give you an injection of a medicine called aminophylline that reduces these effects.

Very common

(*may affect more than 1 in 10 people*)

- headache, dizziness
- shortness of breath
- chest pain
- changes in heart tracing tests (electrocardiogram)
- flushing
- discomfort in the stomach

Common

(*may affect up to 1 in 10 people*)

- heart pain (angina), abnormal heart rhythms, rapid heart beat, feeling the heart skipping a beat, fluttering, or beating too hard or fast (palpitations)
- low blood pressure
- throat tightness, throat irritation, cough
- being sick (vomiting), feeling sick (nausea)
- feeling unwell or weak
- excessive sweating
- pain in the back, arms, legs, neck or jaw
- discomfort in the bones and muscles
- pins and needles, reduced sensation, taste changes
- discomfort in the mouth

Uncommon

(*may affect up to 1 in 100*)

- sudden stopping of the heart or damage to the heart, heart block (a disorder of the heart's electrical signal, where the signal cannot pass from the upper to the lower chambers), slow heart beat
- fits, fainting, mini strokes (including weakness of the face or an inability to speak), reduced responsiveness (which may include a comatose state), trembling, sleepiness
- an allergic reaction which can cause rash, wheals/weals, swelling under the skin near the eyes or throat, throat tightness, difficulty breathing
- wheezing
- rapid breathing
- high blood pressure, paleness, cold extremities
- blurred vision, eye pain
- anxiety, difficulty sleeping
- ringing in the ears
- bloating, diarrhoea, involuntary loss of faeces
- redness of the skin
- pain in the joints
- pain or discomfort around the area injected, body pain

Not known

(frequency cannot be estimated from the available data)

- difficulty in breathing (bronchospasm)
- respiratory arrest

Reporting of side effects

If you get any side effects, talk to your doctor 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 <https://yellowcard.mhra.gov.uk/>.

By reporting side effects you can help provide more information on the safety of this medicine.

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Weight of children.

Do not use Rapiscan after the expiry date which is stated on the vial and carton after EXP. This medicine does not require any special storage conditions.

Rapiscan must not be used if the solution if it is discoloured or particulate matter is present.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment. The healthcare professionals will be responsible for the storage and disposal of this medicinal product.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. CONTENTS OF THE PACK AND FURTHER INFORMATION**What Rapiscan contains**

The active substance in Rapiscan is regadenoson. Each vial of Rapiscan solution for injection contains 400 micrograms of regadenoson in 5 ml solution.

The other ingredients are: disodium edetate, disodium phosphate, sodium dihydrogen phosphate, propylene glycol, water for injections.

What Rapiscan looks like and contents of the pack

Rapiscan solution for injection is a clear, colourless solution with no particles visible. Rapiscan is supplied in a carton containing a single use glass vial with a rubber stopper and aluminium sealed cap. Rapiscan is supplied in a 5 ml or 7 ml glass vial.

Manufacturer

Millmount Healthcare Limited, Block 7, City North Business Campus, Stamullen, Co Meath, K32 YD60 Ireland

Or

Haupt Pharma Wolfratshausen GmbH Pfaffenrieder Str. 5 D-82515 Wolfratshausen, Germany

Or

GE Healthcare AS Nycoveien 1 NO-0485 Oslo Norway

Procured from within the EU and repackaged for the PL Holder: Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom

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For any information about this medicine, please contact the local representative of the Product Licence Holder: Abacus Medicine Ltd. tel: +44(0)2036301244 email: MedInfo@abacusmedicine.co.uk or drugsafetyuk@abacusmedicine.co.uk

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Blind or partially sighted? Is this leaflet hard to see or read? Call 02036301310 or write to info@abacusmedicine.com to obtain the leaflet in a format suitable for you.

The following information is intended for healthcare professionals only:

Rapiscan should be administered as a rapid, 10-second injection into a peripheral vein using a 22-gauge or larger catheter or needle.

5 ml of sodium chloride 9 mg/ml (0.9%) solution for injection should be administered immediately after the injection of Rapiscan.

The diagnostic agent for the myocardial perfusion imaging agent should be administered 10-20 seconds after the sodium chloride 9 mg/ml (0.9%) solution for injection. The diagnostic agent may be injected directly into the same catheter as Rapiscan.

For the measurement of FFR, Rapiscan should be administered as a rapid, 10-second injection into a peripheral vein using a 22-gauge or larger catheter or needle. 10 mL of sodium chloride 9 mg/ml (0.9%) solution for injection should be administered immediately after the injection of Rapiscan. Standard catheterisation and FFR measurement techniques are to be followed, and FFR should be measured as the lowest value of Pd/Pa achieved during steady state maximum hyperemia.

If deemed necessary, a second dose of 400 micrograms can be injected at least 10 minutes after the first dose for FFR measurement during the same catheterization procedure.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

This medicinal product should be inspected visually for particulate matter and discolouration prior to administration.

Any unused product or waste material should be disposed of in accordance with local requirements.

For further information, please refer to the complete Summary of Product Characteristics.