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EPAR summary for the public

Rapiscan

regadenoson

This is a summary of the European public assessment report (EPAR) for Rapiscan. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Rapiscan.

What is Rapiscan?

Rapiscan is a solution for injection that contains the active substance regadenoson.

What is Rapiscan used for?

Rapiscan is for diagnostic use only. It is used in a type of heart scan called 'radionuclide myocardial perfusion imaging' to see the blood flow in the heart muscle.

Before this type of scan, the patient's heart is usually put under stress by exercise such as walking or running on a treadmill to help dilate (widen) the blood vessels in the heart and increase the blood flow to the heart muscle. Rapiscan is used as a 'stress agent' that has a similar effect on the heart as exercise. It is used in adult patients (aged 18 years or over) who are unable to exercise enough for a stress test.

The medicine can only be obtained with a prescription.

How is Rapiscan used?

Rapiscan must only be used in a hospital that has equipment for resuscitation and monitoring the patient.

It is given as a 10-second injection of 400 micrograms into a vein immediately followed by an injection of sodium chloride (salt) solution. The patient then undergoes the procedures for radionuclide myocardial perfusion imaging, starting with an injection of a radioactive substance 10 to 20 seconds

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after the sodium chloride injection. Because Rapiscan causes a rapid increase in heart rate and a fall in blood pressure, patients should remain sitting or lying down and be monitored frequently until the effects of the medicine have worn off.

Rapiscan should only be used once within any 24-hour period. Patients must not take any medicines or products that contain methylxanthines (such as caffeine or theophylline) for at least 12 hours before receiving Rapiscan. They should also stop receiving dipyridamole (a medicine used to prevent blood clots) for at least two days before receiving Rapiscan. For further information on the use of Rapiscan, see the summary of product characteristics (also part of the EPAR).

How does Rapiscan work?

The active substance in Rapiscan, regadenoson, is an A_{2A} adenosine receptor agonist. It works by attaching to A_{2A} adenosine receptors in the walls of the blood vessels in the heart, causing the blood vessels to widen and increasing blood flow into the heart muscle. This enables the blood flow in the heart to be seen more easily during myocardial perfusion imaging.

How has Rapiscan been studied?

In two main studies, around 2,000 adult patients first had a myocardial perfusion imaging scan performed using adenosine (another medicine used as a stress agent) followed by a second scan with either adenosine or Rapiscan. The main measure of effectiveness was based on the similarity between the results of the scans with Rapiscan and adenosine.

What benefit has Rapiscan shown during the studies?

The results of scans using Rapiscan and adenosine were comparable. The ‘agreement rates’ between the first and second scans were similar regardless of which of the two medicines were used for the second scan.

What is the risk associated with Rapiscan?

The most common side effects with Rapiscan (seen in more than 1 patient in 10) are headache, dizziness, ST segment changes (an abnormal reading on the electrocardiogram or ECG), flushing (reddening of the skin), dyspnoea (difficulty breathing), gastrointestinal (stomach and gut) discomfort and chest pain. For the full list of all side effects reported with Rapiscan, see the package leaflet.

Rapiscan must not be used in patients with slow heart rate unless they have a pacemaker, unstable angina (a type of chest pain that changes in severity) that has not been controlled with treatment, severe hypotension (low blood pressure) or decompensated heart failure (when the heart does not work as well as it should). For the full list of restrictions, see the package leaflet.

Why has Rapiscan been approved?

The CHMP decided that Rapiscan’s benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Rapiscan?

A risk management plan has been developed to ensure that Rapiscan is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Rapiscan, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Rapiscan:

The European Commission granted a marketing authorisation valid throughout the European Union for Rapiscan on 6 September 2010.

The full EPAR for Rapiscan can be found on the Agency's website under EMA website/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Rapiscan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2015.