RAPISCAN™ (regadenoson)
ABBREVIATED PRESCRIBING INFORMATION
PRESCRIBERS SHOULD READ THE SUMMARY OF PRODUCT CHARACTERISTICS (SPC)
Each Rapiscan vial contains regadenoson 400 micrograms in 5 mL solution for injection.

INDICATION Use in adults for myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress and the measurement of fractional flow reserve (FFR) of a single coronary artery stenosis during invasive coronary angiography, when repeated FFR measurements are not anticipated.
DOSAGE AND ADMINISTRATION Irrespective of body weight, one 400 microgram vial is injected into a peripheral vein over 10 seconds followed by 5 mL (MPI) or 10 mL (FFR) saline (0.9% sodium chloride) solution flush. The MPI acquisition protocol should be in line with clinical practice guidelines. For FFR, Rapiscan should be administered no more than twice within 24 hours, no less than 10 minutes apart, as full safety data on twice daily administration are not available. FFR should be measured as the lowest value of Pd/Pa achieved during steady state hyperaemia. Patients should avoid consumption of any products containing methylxanthines (e.g. caffeine) as well as any medicinal products containing theophylline for at least 12 hours before. When possible, dipyridamole should be withheld for at least two days before.
CONTRA-INDICATIONS Hypersensitivity to active substance or excipients; patients with second or third degree AV block or sinus node dysfunction who do not have a functioning artificial pacemaker; unstable angina that has not been stabilised with medical therapy; severe hypotension; decompensated heart failure.
PRECAUTIONS Rapiscan has the potential to cause serious and life- threatening reactions. Continuous ECG monitoring should be performed and vital signs monitored at frequent intervals until ECG parameters, heart rate and blood pressure have returned to pre-dose levels. Aminophylline may be used to attenuate severe or persistent adverse reactions, but not for the purpose of terminating a seizure induced by Rapiscan. Fatal cardiac arrest, life-threatening ventricular arrhythmias, and myocardial infarction may result from the ischaemia induced by pharmacologic stress agents like regadenoson. Rapiscan should be used with caution in patients with recent myocardial infarction.
Clinical trials in Single Photon Emission Computed Tomography (SPECT)- MPI excluded patients within 3 months of an acute myocardial infarction. Clinical trials in FFR excluded patients within 5 days of an acute myocardial infarction. Adenosine receptor agonists including regadenoson can depress the sinoatrial (SA) and AV nodes and may cause first, second or third degree AV block, or sinus bradycardia.
Adenosine receptor agonists including regadenoson induce arterial vasodilation and hypotension. The risk of serious hypotension may be higher in patients with autonomic dysfunction, hypovolemia, left main coronary artery stenosis, stenotic valvular heart disease, pericarditis or pericardial effusions, or stenotic carotid artery disease with cerebrovascular insufficiency. Rapiscan may cause clinically significant increases in blood pressure, which in some patients can lead to hypertensive crisis. The risk of significant increases in blood pressure may be higher in patients with uncontrolled hypertension. Consideration should be given to delaying Rapiscan administration until blood pressure is well controlled. Use of Rapiscan involving exercise has been associated with serious adverse reactions including hypotension, hypertension, syncope and cardiac arrest. Patients who have had any symptoms or signs suggestive of acute myocardial ischemia during exercise or recovery are likely to be at especially high risk of serious adverse reactions. Rapiscan can cause transient ischaemic attack. In post-marketing experience there have also been reports of cerebrovascular accident (CVA). Caution should be used when administrating Rapiscan to patients with a history of seizures or other risk factor for seizures, including the concomitant administration of medicinal products that lower seizure threshold (e.g. antipsychotics, antidepressants, theophyllines, tramadol, systemic steroids and quinolones). Aminophylline should be used with caution in patients with a history of seizures or who have other risk factors for seizures as it may prolong a seizure or cause multiple seizures because of its proconvulsant effect. Therefore administration of aminophylline solely for the purpose of terminating a seizure induced by Rapiscan is not recommended. Rapiscan should be used with caution in patients with a history of atrial fibrillation or flutter. In post- marketing experience there have been cases of worsening or recurrence of atrial fibrillation after administration of Rapiscan. Adenosine receptor agonists may cause bronchoconstriction and respiratory arrest. For patients with known or suspected bronchoconstrictive disease, chronic obstructive pulmonary disease (COPD) or asthma, appropriate bronchodilator therapy and resuscitative measures should be available prior to Rapiscan administration. Regadenoson stimulates sympathetic output and may increase the risk of ventricular tachyarrhythmias in patients with a long QT syndrome. This medicinal product contains less than 1 mmol sodium (23 mg) per dose. However, the injection of sodium chloride 9 mg/ml (0.9%) solution given after Rapiscan contains 45 mg of sodium. To be taken into consideration by patients on a controlled sodium diet.
UNDESIRABLE EFFECTS Adverse reactions in most patients were mild, transient (usually resolving within 30 minutes) and required no medical intervention. Rapiscan may cause myocardial ischaemia (potentially associated with fatal cardiac arrest, life- threatening ventricular arrhythmias, and myocardial infarction), hypotension leading to syncope and transient ischaemic attacks, elevated blood pressure leading to hypertension and hypertensive crises, and SA/AV node block leading to first, second or third degree AV block, or sinus bradycardia requiring intervention. Signs of hypersensitivity (rash, urticaria, angioedema, anaphylaxis and/or throat tightness) may be immediate or delayed onset. Aminophylline may be used to attenuate severe or persistent adverse reactions to Rapiscan but should not be used solely for the purpose of terminating a seizure induced by Rapiscan. Very common adverse events reported were dyspnoea, headache, flushing, chest pain, electrocardiogram ST changes, gastrointestinal discomfort, and dizziness. Common adverse events reported were paraesthesia, hypoaesthesia, dysgeusia, angina pectoris, atrioventricular block, tachycardia, palpitations, other ECG abnormalities including electrocardiogram QT corrected interval prolonged, hypotension, throat tightness, throat irritation, cough, vomiting, nausea, oral discomfort, back, neck or jaw pain, pain in extremity, musculoskeletal discomfort, hyperhidrosis, malaise, and asthenia. See SPC for details of other undesirable effects.
PRESENTATION One carton contains a single vial of Rapiscan (400 micrograms regadenoson in 5mL solution for injection).
ATC CODE C01EB21.
MARKETING AUTHORIZATION HOLDER
GB: GE Healthcare Limited, Pollards Wood, Nightingales Lane, Chalfont St Giles, Buckinghamshire HP8 4SP, United Kingdom
NI: GE Healthcare AS, Nycoveien 1, NO-0485 Oslo, Norway.
MARKETING AUTHORIZATION NUMBERS GB: PLGB 00221/0395, NI: EU/1/10/643/001
PRESCRIPTION ONLY MEDICINE
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PRICE £96.81 per vial

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/.
Adverse events should also be reported to GE HealthCare at gpv.drugsafety@ge.com.