3. Warnings and precautions

3.1. Indications for use

Adenoscan should only be used in patients for whom a diagnosis of coronary artery disease is a real possibility.

3.2. Contraindications

Adenoscan should not be used in patients in whom cardiac arrest, sudden onset of angina, or any life-threatening arrhythmia is present.

3.3. Precautions

Adenoscan should be given with caution to patients with a history of allergic reaction to aminophylline or theophylline.

3.4. Special warnings and precautions for use

Adenoscan use in children and adolescents has not been studied.

4. How Adenoscan is given

4.1. Conditions of use

Adenoscan should be given in a standard hospital setting;

4.2. Dosage and method of administration

The table below is given as a guide for adjustment of dosage and blood pressure should be monitored every minute.

4.3. Duration of treatment

The duration of treatment should be decided by a physician. In general, the procedure should not last longer than 10 minutes.

4.4. Incompatibilities

In the absence of compatibility studies, this medicinal product should not be mixed with:

- Sodium chloride

- Aminophylline
- Theophylline

5. Uses in special populations

5.1. Pregnancy

Adenoscan should be used during pregnancy only if clearly needed. Its use in pregnancy is not recommended.

5.2. Breast-feeding

Adenoscan should not be used during breast-feeding.

6. Summary of clinical pharmacology

6.1. Pharmacokinetics

Adenoscan has not been studied extensively for its pharmacokinetics. It is rapidly absorbed.

6.2. Mechanism of action

Adenoscan produces a relex increase in heart rate occurs later than the peak positive inotropic effect. This effect is mainly due to the activation of adenylate cyclase through A2 receptors in vascular smooth muscle and myocytes. The half-life of Adenoscan in vitro is 120 seconds, and in vivo it is 40-50 seconds.

6.3. Clinical trials

Adenoscan use in children and adolescents has not been studied.

7. Adverse reactions

Common (may affect up to 1 in 10 people)

• Feeling drowsy
• Feeling dizzy or light-headed
• Feeling breathless
• Chest pain

Uncommon (≥1/1000, <1/100)

• Feeling faint
• A sudden numb or weak feeling in the face, arms, or legs

Rare (≥1/10000, <1/1000)

• Nausea

Very rare (<1/10000), Very rare (<1/100000), Not known (cannot be estimated from studies involving only 10000 persons or less),</p>
Adenoscan contains a medicine called adenosine. This belongs to a group of medicines called vasodilators.

1. WHAT ADENOSCAN IS AND WHAT IT IS USED FOR

1.1. Name of the medicinal product

Adenoscan is a medicine given by a doctor or nurse to help check blood flow in the heart. Adenoscan is intended for use in hospitals with the help of a specialist doctor.

1.2. Qualitative and quantitative composition

Adenoscan contains:

Adenosine 2 mg/ml


diluent: (10ml)

2. PHARMACOLOGICAL PROPERTIES

2.1. Pharmacodynamic properties

Adenoscan causes a dose-dependent fall in behaviour of the autonomic nervous system.

2.2. Pharmacokinetic properties

The increase in blood flow caused by Adenoscan in stenotic arteries. Adenoscan redirects coronary blood flow from the endocardium to the epicardium and may cause blood flow velocity returns to basal levels within six minutes through an infusion pump (a slow injection).

3. HOW TO TAKE ADENOSCAN

3.1. Method of administration

Adenoscan is given by a doctor or nurse through a tube (catheter) placed in your vein. You may receive up to 0.99mg of sodium per minute.

3.2. Amount to be administered

The dose is calculated according to your weight. Usually, only 0.1mg of adenosine is given during one Adenoscan infusion.

3.3. Duration of effect

The effects of Adenoscan usually last for three to six minutes.

3.4. Special precautions for storage

Adenoscan should be stored in a refrigerator (2°C to 8°C).

3.5. Date of first authorisation/review of the NDA

This medicine will be kept by your doctor or nurse or pharmacist in a safe place where children cannot see or reach it.

4. POSSIBLE SIDE EFFECTS

4.1. List of adverse reactions

Adenoscan can cause side effects which may affect individual organs or body systems. The side effects of Adenoscan are listed below.

Very common: abdominal discomfort

Common: urine urgency

Uncommon: feeling of weakness or pain, or of general discomfort

Very rare: ST segment depression, ventricular fibrillation

4.2.Effects related to the known pharmacology of adenosine

Adenosine is metabolized by adenosine kinase to adenosine monophosphate, or by adenosine deaminase to inosine. Adenosine is a vasodilator/antiarrhythmic agent. It acts on cardiac and smooth muscle. Adenosine is a coronary vasodilator. Adenosine acts on the heart to produce a mild dose-dependent fall in mean arterial pressure. Adenosine has a vasodilator/antiarrhythmic effect on stomach, small intestine, renal artery, aorta, and the heart. Adenosine effects in renal and splanchnic vessels are small and limited to the afferent arterioles and the coronary and pulmonary vessels.

5. INTERACTIONS

5.1. General

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

5.2. Medicines

Adenoscan may interact with other medicines. Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

6.1. Description

Adenoscan is available as a ready-to-use solution for infusion.

6.2. Shelf life

The shelf life of the unopened product is 3 years.

6.3. Shelf life

7. MARKETING INFORMATION

7.1. Name of the marketing authorisation holder

8. REPRODUCTIVE CAPACITY

This medicine is for diagnostic use only. Adenoscan contains a medicine called adenosine. This belongs to a group of medicines called vasodilators.

9. LEGAL CATEGORY

This medicine is available without medical supervision.

10. PROFESSIONAL SAFETY INFORMATION

This medicine is available without medical supervision. Adenoscan is not recommended for use in children.

11. CONDITIONS PRECEDING USE

11.1. Conditions before use

Adenoscan should not be used if your doctor or nurse does not consider you to be a suitable patient.

12. EFFECTS OF OVERDOSE

If you have more of this medicine than you should, the effects of overdose may include:

- Feeling dizzy or light-headed
- Feeling of weakness or pain, or of general discomfort
- Discomfort in leg, arm or back

13. DISPOSAL OF LEFTOVERS

13.1. Disposal of the container and packaging

Adenoscan should not be given to anyone else (other than in accordance with the instructions on the label or in your doctor’s instructions).

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

14. INDICATIONS AND CONTRAINDICATIONS

14.1. Indications

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

14.2. Contraindications

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

15. DOSAGE AND ADMINISTRATION

15.1. Dosage

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

15.2. Administration

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

16. HOW TO USE ADENOSCAN

16.1. Method of administration

Adenoscan is not recommended for use in children.

16.2. Duration of effect

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

17. ADVERSE REACTIONS

17.1. Description

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

17.2. List of adverse reactions

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

17.3. Frequency of adverse reactions

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

17.4. Description of adverse reactions

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18. CHEMICAL INFORMATION

18.1. General

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.2. Molecular formula

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.3. Molecular weight

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.4. Structural formula

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.5. Substance

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.6. Physical state

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.7. CAS number

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.8. EINECS number

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.9. ELINCS number

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.10. Common name

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.11. Chemical name

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.12. Synonyms

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.13. Toxicological properties

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.14. Hazardous properties

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.15. PBT or vPvB properties

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.16. Environmental effects

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.17. Human health effects

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.18. Ecotoxicological effects

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.19. Substance transport information

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.20. Disposal information

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.21. Transport information

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.22. Technical control measures

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.

18.23. Data sources

Adenoscan should be used with caution in patients with severe heart disease and in those with a history of heart problems.