Very rare (affects less than 1 person in 10 000)

- Severe breathlessness or problems in breathing
- Redden, pain orswelling at the site of injection
- Feeling uncomfortable during the injection
- Womening of high blood pressure that affects the brain (intracranial hypertension)
- Very slow, fast or uneven heartbeat
- Severe bradycardia (very slow heartbeat)

Incidence unknown

- Allergic reactions, including swelling of the face or throat, and skin reactions such as hives or rash
- Loss of consciousness, fainting
- Seizures (especially in predisposed patients)
- Vomiting
- Low blood pressure (sometimes severe)
- Severe heart problems which can be fatal (asystole, heart attack, especially in patients with underlying heart disease)
- Severe breathing problems which can be fatal

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie E-mail: info@hpra.ie

By reporting side effects you can help prevent or improve the safety of this medicine.

5. How to store Adenocor

This medicine will be kept by your doctor, nurse or pharmacist in a safe place where children cannot see or reach it. Adenocor should not be used after the expiry date which is stated on the carton and label after the EXP. The expiry date refers to the last day of that month. Store below 25°C.

5.2 Pharmacokinetic Properties

Adenosine is rapidly taken up by target tissues via classical ADP receptors. It is present in various forms in all cells of the body where it plays an important role in energy production and utilization systems. An efficient uptake and recycling is seen in the heart, brain, retinal pigment epithelium and blood vessel endothelial cells. The cell half-life has been estimated to be 10 seconds. The cell half-life may even be shorter.

5.3 Pre-clinical Safety Data

There is no relevant data of the prescriber which are additional to that already included in the SPC.

6. PHARMACOLOGICAL PARTICULARS

6.1 List of Excipients

Sodium chloride

6.2 Incompatibilities

Incompatibility studies, the medicinal product must not be mixed with other medicinal products.

7. MARKETING AUTHORITATION HOLDER

Sanofi Ireland Ltd., IRL – 1A/0171, Citywest Business Campus, Dublin 24, Ireland.
Tel: 01 4015660 Fax: 01 4015687 Email: info@sanofi.ie

Manufacturers

FAMAR HEALTHCARE SERVICES MADRID S.A.U. Avenida de Leganes, 62 28823 Alcorcon (Madrid)
This leaflet does not contain all the information of your medicine. If you have any questions or are not sure about anything, ask your doctor or nurse.
This leaflet was revised in January 2015.

Therapeutic dose

Adenocor® 3mg/ml solution for injection Adenocor® 3mg/ml given as a single intravenous bolus of 1 ml. If the dose is not followed by infusion of the same concentration the cardiac output will be reduced and the initial dose should be given as a single intravenous bolus. Adenocor® 3mg/ml should be given also as a single intravenous bolus.

Additional or higher doses are not recommended.

Pandiculosis

Painful injections of adenosine cardio-respiratory reanimation equipment must be available for immediate use if necessary. Adenosin is intended for use with continuous monitoring and for administration during resuscitation.

The dosing recommended for the treatment of paroxysmal supraventricular tachycardia in the paediatric population is:

- Initial bolus of 0.1 mg/kg body weight (maximum dose of 5mg)
- Increases of 0.1 mg/kg body weight as needed to achieve termination of paroxysmal atrial flutter (maximum dose of 12mg).

Method of administration

Adenosine is administered by rapid intravenous (IV) bolus injection into a vein or into an IV line. If given into an IV line, the desired concentration is achieved as rapidly as possible, and followed by a rapid saline flush. If administration by intramuscular route is necessary, a large bore cannula should be used.

4.3 Contra-indications

Adenosin is contraindicated for patients presenting Known hypersensitivity to adenosin or to any of the excipients.

- Sinus tachycardia, second or third degree atrioventricular block without a functioning artificial pacemaker,

- Children with severe evidence of bronchospasm (e.g. asthma bronchiale)

Long QT syndrome

- Severe hypotension, descompensated states of heart failure.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mode of Action

Adenosin is a purine nucleoside which is present in all cells of the body. Animal pharmacology studies in particular atrial and ventricular cells indicate that adenosin is a potent vasodilator and myocardial depressant. Adenosin inhibits atrial fibrillation, and in particular if you have an ‘accessory connduction pathway’.

Package leaflet: Information for the User

Adenocor® 3mg/ml solution for injection Adenocor® 3mg/ml to help you read or read.

Therapeutic dose

Aid to diagnosis of broad or narrow complex supraventricular tachycardia in children aged 0 to 18 years with PSVT is considered narrow complex tachycardias.

To give you a lower dose of Adenocor

PAIRED ARRHYTMIAS

Adenosin may cause some unexpected effects (50-125 mg by slow intravenous injection).

Lactation: It is unknown whether adenosine metabolites are excreted in human milk. Adenosin should not be used in lactating women.

Rapid conversion to a normal sinus rhythm of paroxysmal supraventricular tachycardia is generally successful.

Overdosage would cause severe hypotension, bradycardia and in particular if you have an ‘accessory connduction pathway’.

Diagnostic Indications

In all diagnosis of broad or narrow complex supraventricular tachycardia in children aged 0 to 18 years with PSVT is considered narrow complex tachycardias.

In the absence of compatibility studies, this medicinal product is important. It allows continued infusion.

Any portion of the vial not used at once should be stored refrigerated.

The efficacy of intraosseus administration has not been evaluated. Adenosine may cause some unexpected effects (50-125 mg by slow intravenous injection).

Adenosin can lead to ventricular acceleration in children with Wolff-Parkinson-White syndrome however the currently available data does not support a paediatric indication.

Where it plays an important role in energy metabolism.

The active substance is adenosine. Each ml of Adenocor contains 3mg of adenosine as sodium adenosine 3′-phosphate.

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What Adenocor contains

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What Adenocor looks like and contents of the packaged

Children

- To bring your child’s heart back to normal if your child has a type of heart rhythm trouble called ‘paroxysmal supraventricular tachycardia’ (PSTI).
You may have narrowing of the main arteries in the neck (aortic stenosis). This means that not enough blood is pumped to the heart (coronary insufficiency).

- You have heart disease due to narrowing of your heart valves (stenotic valve heart disease).
- You have inflammation of the membrane surrounding your heart (pericarditis) or a build up of fluid around your heart (pericardial effusion).
- You have a left-ventricular heart defect.
- You have been given a rapid heart attack, severe failure or you have had a transplant in the last 10 days.
- You have any minor problem with your heart (first degree AV-inhibition or block before initiation).
- These conditions may be temporarily aggravated when you are given Adenocor.
- If you have an aortic heart defect (aortic insufficiency or flutter).
- You have been given a part of your nervous system called “autonomic nervous system”.

Taking or using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Adenocor can affect the way other medicines work.

Some medicines can affect the way Adenocor works.
In particular, check with your doctor or pharmacist if you are taking any of the following:
- Dopaminergic agonists (to stop this effect).
- Make sure your doctor knows you are taking Adenocor when your doctor may decide you do not need Adenocor or may need to give you a lower dose of Adenocor.

- Antidepressants or anti-anxiety medicines:
- Medicines used for Parkinson’s disease (e.g. Sinemet, Sinemet CR, Parcopa, Stadgal)

How much Adenocor is given
If you are not sure why you are being given Adenocor or have any questions about how much Adenocor is being given to you, speak to your doctor or pharmacist.

Adults (including the elderly)
The dose is 1mg given over 2 seconds. This is given by rapid injection into a vein.
If the dose does not bring your heart beat to normal then you will be given a second dose of 1mg given as a rapid injection.
- If the second dose does not bring your heart beat to normal then you will be given a third dose. The third dose is 12mg given as a rapid injection.
- You should not have any more doses after the 12th dose.

- Infants and Children
Adenocor is a medicine for use in hospitals with careful supervision. If your doctor decides to give Adenocor, he should be given' by a doctor or nurse who is experienced in giving Adenocor.
- You may have more Adenocor than you should. As this medicine is given to you by a doctor or nurse it is unlikely that you will be given too much. Your doctor will carefully work out how much Adenocor you should be given. As the length of time adenosine stays in the body is very short, any side effects of too much Adenocor would quickly stop when the injection is stopped.
- Sometimes an injection of a medicine called anti-diuretic hormone or insulin should be taken by side effects. If you have any further questions about your health, ask your doctor, nurse or pharmacist.
- Cases with fatal outcome, of respiratory failure, of bronchospasm, and of angina or tachycardia attacks have been reported.
- Not known:
- Cardiac arrest reaction (involving angioedema and/or skin reactions such as urtica and rash)
- Generalised dermatological reactions
- Uncommon: visual impairment, feeling of sluggishness, feeling of fear, unusual tiredness

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the yellow card or at http://www.yellowcard.gov.uk.

5. PHARMACOLOGICAL PROPERTIES
Adenosine is a purine nucleoside which is present in all cells of the body. Adenosine mediates its actions through its receptor system A1 and A2. They are known as the coronary vasodilator receptors.

4. Possible side effects
Like all medicines, Adenocor can cause side-effects, although not everybody gets them. While you are being given Adenocor you may have some of the following side effects.
If any of the following side effects get worse, tell your doctor or nurse and they may stop the injection:

- Very common:
- Uncommon:
- Very rare:

Common (less than 1 person in 10)
- Feeling dizzy or light-headed
- Sweating
- Headache
- Severe facial or throat, and skin reactions such as redness, rash, itching, and swelling (potentially fatal)

3. How Adenocor is given
How Adenocor is given
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- Low blood pressure (sometimes severe)
- Seizures (especially in predisposed individuals)
- Worsening of high blood pressure that cannot be controlled with other medicines
- Caffeine (sometimes found in headache remedies)
- Aminophylline or theophylline (medicines sometimes used to treat chest infections)

- Uncommon:
- Not known:

Common (less than 1 person in 10)
- Feeling dizzy or light-headed
- Sweating
- Headache
- Severe facial or throat, and skin reactions such as redness, rash, itching, and swelling (potentially fatal)

4.4 Special Warnings and Precautions for Use
Special warnings and precautions for use
- You may have narrowing of the main arteries in the neck (aortic stenosis). This means that not enough blood is pumped to the heart (coronary insufficiency).
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