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FOCUS Focus Pharmaceuticals Ltd

Package leaflet: Information for the patient

Adcus™ 3mg/ml Solution for Infusion

Adenosine

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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet.

What is in this leaflet:

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

1.What Adcus is and what it is used for

Adcus™ 3mg/ml Solution for Infusion (called Adcus throughout the rest of this leaflet) belongs to a group of medicines called coronary vasodilators.

Adcus is given with other medicines, called radionuclides, during a diagnostic test, called myocardial perfusion imaging, to open up your heart's blood vessels to allow your blood to flow more freely. Once in your blood, the radionuclide allows the doctor or nurse to see your heart and assess your heart condition.

This medicine is for diagnostic use only and is used if you are incapable of exercise. You will usually be in hospital when you receive this medicine.

2.What you need to know before you are given Adcus

Do not have Adcus
- if you are allergic to adenosine or any of the other ingredients of this medicine (listed in section 6);
- if you have an irregular heart rhythm and do not currently have a pacemaker fitted;
- if you have a disorder that affects the heart's electrical activity (Long QT syndrome);
- if you have very low blood pressure (severe hypotension);
- if you have unstable angina (severe chest pain) that is not currently controlled by either treatment or medication;
- if you have a type of heart failure where your heart does not pump out enough blood;
- if you have asthma or any other severe breathing problems;
- if you have taking a medicine called dipyridamole, used to thin the blood.

Tell your doctor or nurse if any of the following apply to you:
- if you have recently had a heart attack, heart failure, or you have had a heart transplant within the last year;
- if you have a low blood volume level that has not been corrected by either treatment or medication;
- if you have a type of heart disease caused by the narrowing of your heart valves;
- if your heart is inflamed, enlarged, or you have fluid around your heart;
- if you have seizures or convulsions (fits);
- if you have difficulty breathing;
- if you suffer from problems with your autonomic nervous system;
- if you suffer from a narrowing of the main arteries in your neck (carotid arteries) that prevents sufficient blood getting to your brain;
- if you have a known heart defect;
- if you have an unusual heart rhythm (atrial fibrillation or flutter).

Using other medicines

Make sure your doctor or nurse knows if you are taking, or have recently taken, any of the medicines listed here:
- **Dipyridamole** (used to thin the blood); taking dipyridamole at the same time as Adcus will increase the effect of adenosine on the body. Your doctor or nurse may decide not to give you Adcus, may tell you to stop taking dipyridamole 24 hours before you are given Adcus, or they may lower the dose.
- **Aminophylline** and **theophylline** (used to help breathing difficulties), or medicines containing **Xanthines (caffeine)**, which are found in certain medicines used to treat headaches. Your doctor may tell you to stop taking these medicines 24 hours before you are given Adcus.
- Medicines that affect the rate at which your heart conducts electrical impulses such as **calcium channel blockers** e.g. diltiazem and amlodipine, **beta- adrenergic blocking agents** e.g. propanolol and metoprolol and **centrally acting agents** e.g. clonidine and guanfacine.

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

Taking Adcus with food and drink
- Where possible, do not drink or eat products containing caffeine, such as tea, coffee, chocolate, or cola, for at least 12 hours before you are given Adcus.

Pregnancy and breast-feeding
- If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or nurse for advice before they give you this medicine.
- You should not be given this medicine if you are breast-feeding.

Important information about some of the other ingredients in Adcus
- Your medicine contains **sodium (salt)**. This medicinal product contains 3.54mg (0.15mmol) of sodium (salt) per 1ml of solution. To be taken into consideration by patients on a controlled sodium (salt) diet.

3.How you will be given Adcus

You will usually be in hospital when you are given Adcus. You will be given it by a doctor or nurse, as an infusion, into your vein. Your heart and blood pressure will be closely monitored.

Adults and the elderly
- The dose is based on your body weight.
- Your doctor or nurse will decide how much to give you.
- The usual dose is 140 micrograms per kilogram, per minute, given over a period of six minutes.

Technical Leaflet intended for healthcare professionals only

ADCUS™ 3MG/ML SOLUTION FOR INFUSION

GENERAL INFORMATION

Adcus™ 3mg/ml Solution for Infusion is for single use only. Any portion of the vial, not used at once, should be discarded.

THERAPEUTIC INDICATIONS

Intravenous (IV) Adcus™ 3mg/ml Solution for Infusion is a coronary vasodilator, for use in conjunction with radionuclide myocardial perfusion imaging, in patients who cannot exercise adequately or for whom exercise is inappropriate.

Adcus™ 3mg/ml Solution for Infusion is indicated in adults.

POSOLOGY AND METHOD OF ADMINISTRATION

Adcus™ 3mg/ml Solution for Infusion is intended for use in hospitals. It should be administered following the same procedure as for exercise testing, where facilities for cardiac monitoring and cardio-respiratory resuscitation are available for immediate use, if necessary.

During administration of Adcus™ 3mg/ml Solution for Infusion, continuous electrocardiogram (ECG) control is necessary, as life-threatening arrhythmia might occur. Heart rate and blood pressure should be monitored every minute.

Adults:

1.Adcus™ 3mg/ml Solution for Infusion should be administered undiluted, as a continuous peripheral intravenous infusion, at a dose of 140 µg/kg/min for six minutes using an infusion pump. Separate venous sites for Adcus™ 3mg/ml Solution for Infusion and radionuclide administration are recommended to avoid an adenosine bolus effect.

2.After three minutes of infusion of Adcus™ 3mg/ml Solution for Infusion, the radionuclide is injected to ensure sufficient time for peak coronary blood flow to occur. The optimal vasodilator protocol is achieved with six minutes of infusion of Adcus™ 3mg/ml Solution for Infusion.

3. To avoid an adenosine bolus effect, blood pressure should be measured in the arm opposite to the infusion of Adcus™ 3mg/ml Solution for Infusion.

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Children

The safety of Adcus in children is not known. Therefore, it is not recommended for use in children. If the doctor or nurse decides that this medicine is needed, they will determine the most appropriate dose to give.

If you are given too much Adcus

As this medicine is given to you by a doctor or nurse, it is unlikely that you will be given too much. However, if you are given too much medicine, the following side effects may occur:
- an extreme lowering in blood pressure;
- a lowering in heart rate;
- a heart problem.

Adenosine stays in the blood for a very short period of time. Therefore, any side effects would soon subside once the infusion has been stopped. You may be given a medicine called aminophylline or theophylline to help with any side effects experienced.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4.Possible side effects

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

If you experience any of the following side effects after you have been given your medicine, tell your doctor or nurse immediately. If you are not in hospital, you MUST GO straight away.
- **Severe allergic reaction** which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**
- **Severe chest pain.**
- **An extreme lowering in heart rate.**
- **An extreme lowering in blood pressure.**
- **Respiratory failure.**

Very common side effects (may affect more than 1 in 10 people):
- chest pain or pressure on the chest
- flushing (sudden reddening of the skin accompanied by the feeling of heat)
- shortness of breath or the urge to take a deep breath
- headache
- abdominal discomfort

Common side effects (may affect up to 1 in 10 people):
- low blood pressure
- irregular heart rhythms
- dizziness or feeling light headed
- throat, neck or jaw discomfort
- dry mouth
- numbness, tingling, prickling or burning of the skin

Uncommon side effects (may affect up to 1 in 100 people):
- apprehension (feeling nervous)
- metallic taste in your mouth
- feeling of general weakness, discomfort or pain
- sweating
- slow heartbeat

Rare side effects (may affect up to 1 in 1000 people):
- blurred vision
- nipple discomfort
- ringing or buzzing in your ears (tinnitus)
- feeling the sudden need to urinate
- drowsiness
- blocked nose
- difficulty breathing
- shaking (tremors)

Other side effects which may occur:
- fainting or loss of consciousness
- convulsions (fits)
- cardiac arrest (a sudden loss of heart function)
- stopping breathing (respiratory failure or arrest)
- fast, uneven or abnormal heartbeat
- asystole (a severe and fatal heart problem)
- nausea (feeling sick) or vomiting (being sick)

Very rare effects which may occur at the site of injection (affecting up to 1 in 10,000 people):
- redness
- itching
- pain
- abscesses
- swelling
- swollen and painful veins

You will be observed by medical staff at all times, whilst being given Adcus, to monitor the effects on your heart.

If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

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5.How to store Adcus

This medicine will be stored, by your doctor, nurse or pharmacist out of the sight and reach of children.

This medicine should not be used after the expiry date stated on the carton and vial label. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

This product is for single use only. Once your doctor or nurse has opened the vial, it should be used immediately. Any remaining Adcus must be thrown away by the doctor or nurse.

6.Contents of the pack and other information

What Adcus contains
- The active substance is adenosine. Each 10ml vial contains 30mg adenosine (3mg per ml).
- The other ingredients are sodium chloride and water for injections.

What Adcus looks like and contents of the pack.

Adcus is a clear, colourless solution in a clear, glass vial. Each vial contains 10ml of medicine. This product is available in cartons containing 6 x 10ml vials.

Marketing Authorisation Holder

Focus Pharmaceuticals Limited, Unit 5, Faraday Court, Centrum 100, Burton upon Trent, Staffordshire, DE14 2WX, UK.

Manufacturer

Vianex S.A., Plant A, 12km National Road Athinon-Lamias, Metamorfosi Attiki, 14451, Greece.

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom:	Adenosine 30mg/10ml Solution for Infusion
Ireland:	Adcus™ 3mg/ml Solution for Infusion
Greece:	ADENORYTHM® 3mg/ml Διάλυμα για έγχυση

This leaflet was last revised in January 2012.

Other sources of information

For information in large print, audio CD or Braille please telephone 00 44 (0)1283 495 280 or email medinfo@focuspharma.co.uk.

The table below is given as a guide for adjustment of the infusion rate of undiluted Adcus™ 3mg/ml Solution for Infusion, in line with bodyweight (total dose 0.84 mg/kg).

Patient Weight (kg)	Infusion Rate (ml/min)
45 - 49	2.1
50 - 54	2.3
55 - 59	2.6
60 - 64	2.8
65 - 69	3.0
70 - 74	3.3
75 - 79	3.5
80 - 84	3.8
85 - 89	4.0
90 - 94	4.2
95 - 99	4.4
100 - 104	4.7

Paediatrics:

The safety and efficacy of Adcus™ 3mg/ml Solution for Infusion in children aged 0-18 years old have not been established. No data are available. Therefore, use in children cannot be recommended.

Elderly:

See dosage recommendations for adults.

STORAGE AND DISPOSAL OF ADCUS™ 3MG/ML SOLUTION FOR INFUSION

This medicinal product does not require any special storage conditions.

The product should be inspected visually for particulate matter and colouration prior to administration. Where the visual appearance of the product may have changed, the vial should be discarded.

Dispose of any remaining solution after a single use. Any unused product or waste material should be disposed of in accordance with local requirements.

Shelf life:

Unopened: 2 years.

Once opened, the product should be used immediately.

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		FOCUS VERSION 4 08/02/2012
Focus Contact: Katie Murfin	Signature: (Proof Reader) Date:	Signature: (Regulatory) Date:
Product Description/Component: Adcus™ Solution for Infusion 3mg/ml - PIL - IE	Signature: (Marketing) Date:	Signature: (Braille) Date:
Market: Ireland	File Name: Adcus_3mgml_SolINF_PIL	Part No/Component Code: -
Supplier / Manufacturer: XXXXX	Printer / Repro: XXXXX	Software Package: Adobe Illustrator CS3
Substrate: Paper	Cutter Ref: -	PL No.: PL 20046/0091
Barcode:	Dimensions: 158mm x 350mm (Portrait)	Minimum Point Size: 6.75pt (technical area)
Keys: Dieline ● Print Free ○	Pantone/ Process Cols Used: P 302	

Reason for new version:
V1. Separate IE PIL created. V2. Various text amends throughout. V3. Minor text amend. V4. Text amend section 5

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