4.7 Effects on Ability to Drive and Use Machines

It is not recommended during pregnancy unless the physician feels it is necessary. There is no evidence to suggest that Adenocor has any effect on the breast feeding mother. This medicine has not been studied in children.

4.8 Pseudology and Method of Administration

Adenosine is intended for hospital use only with monitoring and cardiological assistance. The equipment available for immediate use. It should be admnistered by rapid IV bolus injection according to the following dose and volume. To hypnotise the solution reaches the systemic circulation adenosine either directly into a venous or into an IV line. If given into an IV line it should be injected as quickly as possible and followed by a rapid saline flush. Adenosine should only be used when facilities exist for cardiac monitoring. Patients who develop high blood block at a particular dose should not be given further dose increments.

4.9 Overdose

If any of the following side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist:

- Uneven heartbeat
- Head pressure
- Sweating
- Bronchospasm (e.g. asthma bronchiale)
- Long QT syndrome
- Severe hypertension, decompensated states of heart failure.

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4.10 Adriamycin/bouquet syndrome

5. PHARMACOLOGICAL PROPERTIES

6. Further information

What Adenocor contains

- 1 -   11504021-00

6.1 List of Excipients

- 1 -   11504021-00

6.1.1 Sodium chloride

6.2 Incompatibilities

6.3 Nature and Contents of Container

6.4 Special Precautions for Disposal and other

6.5 Special Precautions for Storage

7. HOW TO USE ADENOCOR SOLUTION FOR INJECTION

8. MARKETING AUTHORITY NUMBER

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

Date of first authorization: 16th June 1994
Date of renewal: 16th June 2003

10. Date of Revision

Package Leaflet: Information for the User

Adenocor 3mg/ml solution for injection Adenosine

1. NAME OF MEDICAL PRODUCT

Adenosine 3mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 3mg of adenosine per 2ml (3mg/ml). Each vial also contains 3.53mg sodium per 2ml (1.765mmol).

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection

A clear, colourless solution.

Sodium: Adenocor contains 3.53mg sodium per 2ml. Sodium chloride

6.1 List of Excipients

- 1 -   11504021-00

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Solution for injection

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Sodium: Adenocor contains 3.53mg sodium per 2ml. Sodium chloride
In patients with history of convulsions/seizures, the Adenosine may trigger convulsions in patients who are asystole/cardiac arrest (potentially fatal), should lead to hypotension, respiratory failure (potentially fatal), or the product (see Section 4.2 Posology and Method of Administration).

The occurrence of respiratory failure (potentially fatal), hypotension, severe bradycardia and severe asystole have been observed.

Adenosine should be used with caution in patients with atrial fibrillation or flutter and especially in those with an acquired left atrial hypertension that might develop in the background of atrial fibrillation.

Adenosine should not be used in patients with recent myocardial infarction or severe heart failure. Adenosine should be used with caution in patients with minor conduction defect (first degree AV block), bundle branch block that could be transmitted aggrandized during infusions.

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