**INFORMATION FOR THE HEALTHCARE PROFESSIONAL**

**Name of the Medicinal Product**
Aprotinin 10,000 KIU/ml Injection BP

**Qualities and Guarantees**
Each vial contains a minimum of 10,000 Kallikrein Inactivator Units (KIU) of aprotinin in 50ml of sodium chloride solution.

**Pharmaceutical Form**
Solution for Injection

**Posology and Method of Administration**
An appropriate aprotinin-specific dilution chart may be considered before administration of aprotinin (see section 4.4 of the Summary of Product Characteristics). Aprotinin Injection will only be given by your doctor if you have been given in dilute test doses to check you are suitable to get an appropriate aprotinin-specific IgG antibody test and to determine how often aprotinin may be a safer alternative for you.

**Pregnancy and breast-feeding**
Aprotinin Injection if it is past the expiry date on the packaging. If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

**INFORMATION FOR THE PATIENT**

**What is this leaflet about?**
Aprotinin Injection belongs to a group of medicines called anti-fibrinolytics, i.e. medicines to prevent blood loss.

**What is Aprotinin Injection?**
Aprotinin Injection can help to reduce the amount of blood loss you have during and after heart surgery. It is also used to reduce the need for a blood transfusion during and after heart surgery. Your doctor/surgeon has decided that you would benefit from Aprotinin Injection treatment because you are at increased risk of major blood loss since you will undergo a heart bypass operation using a circulation outside your body (heart-lung machine).

Your doctor will administer aprotinin after careful consideration of the benefits and risks, and the availability of alternative treatments.

**What is the dose of aprotinin?**
- If you have allergic to Aprotinin Injection or any of the other ingredients of this medicine (listed in section 6).
- If you have a reduced kidney function or a kidney failure.
- If you have or suspect you have received aprotinin or any of the other ingredients of this medicine (listed in section 6).

**What is in this leaflet:**
1. What aprotinin Injection is and what it is used for
2. How to use Aprotinin Injection
3. Possible side effects
4. How to store Aprotinin Injection
5. Contents of the pack and other information

**What you need to know before you are given Aprotinin Injection**
You must not be given Aprotinin Injection:
- If you are allergic to aprotinin or any of the other ingredients of the medicinal product in the last 12 months.
- If you are allergic to any of the ingredients of this medicinal product.
- If you have kidney problems or kidney failure.
- If you have or suspect you have received aprotinin or any of the other ingredients of this medicinal product.

**Possible side effects**
• You may experience:
  - feeling sick
  - itching, rash and hives
  - reduced blood pressure
  - severe allergic reaction (anaphylactic shock), which is very rare.
You must not be given Aprotinin Injection

Aprotinin Injection

2 What you need to know before you are given

Your doctor will administer aprotinin after careful
treatment because you are at increased risk of major
decided that you would benefit from Aprotinin Injection
also used to reduce the need for a blood transfusion
to reduce the amount of anti-fibrinolytics, i.e. medicines to prevent blood loss.

12 months.

available, showing an increased risk of an allergic
other ingredients of this medicine (listed in section 6).
(see section 4.3 of the Summary of Product Characteristics).

Pharmaceutical Form

sodium chloride solution.

substrate for neutrophils.

You have or suspect you have received aprotinin or
Your kidneys do not work properly.

10,000 KIU) test dose should be administered to all patients

Aprotinin must be given only to patients in the supine
position and must be given slowly (injection rate ≤ 0.15
millilitre per minute) as an intravenous injection or as a short infusion.

Very rare: may occur up to 1 in 10,000 patients
- swelling on or around the location of the injected skin
injection site reactions; infection (injection site infections)

You can also report side effects directly via the national reporting system in the UK.

You will be monitored carefully for any allergic reaction.
Aprotinin Injection will only be given if your doctor has
recommended dose

Aprotinin Injection is a sterile, clear colourless solution. It

Aprotinin Injection also contains the inactive ingredient
calcium chloride.

If the vial is clear and not opalescent, the medicinal product
is lost.

This leaflet was last revised in 04/2014 (April 2014)

The marketing authorisation holder is
Nordic Pharmaceuticals Ltd.,
Abbey House,
Incisive House,
Nordic Pharma Ltd.,
Abbey House,
Nordic Pharmaceuticals Holding A/S,
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