

PACKAGE LEAFLET  
**Syner-KINASE®**  
INFORMATION FOR THE USER

Syner-KINASE® 10,000 IU

Syner-KINASE® 25,000 IU

Syner-KINASE® 100,000 IU

Syner-KINASE® 250,000 IU

Syner-KINASE® 500,000 IU

Powder for solution for injection or infusion

**Read all of this leaflet carefully before you start taking/using this medicine. It contains a summary of the information available on Syner-KINASE. The information in this leaflet applies only to your medicine.**

- keep this leaflet. You may need to read it again
- if you have further questions, please ask your doctor or your pharmacist
- this medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- if any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor

**This leaflet answers the following questions:**

- 1. What Syner-KINASE is and what it is used for**
- 2. Before you are given Syner-KINASE**
- 3. How Syner-KINASE is given**
- 4. Possible side-effects**
- 5. How to store Syner-KINASE**
- 6. Further information**

- 1. What Syner-KINASE is and what it is used for:**

The name of your medicine is Syner-KINASE. The active ingredient is urokinase, a thrombolytic that can help to dissolve blood clots that may form in:

- intravenous catheters or cannulae (surgical tubes used to withdraw fluids from, or introduce fluids into the body)
- lungs
- deep veins
- peripheral arteries (blood vessels away from the heart, such as in the leg)

## **2. Before you are given Syner-KINASE:**

### **Syner-KINASE will not be given to you if you:**

- are allergic (hypersensitive) to urokinase or any of the other ingredients of Syner-KINASE (See Section 6)
- are currently bleeding
- had a major surgical operation or a stroke recently (in the past 2 months)
- have severe high blood pressure
- have abnormal blood clotting
- have abnormal blood vessels
- have cancer of the brain
- have infection of the pancreas or heart
- have severe liver or kidney disease

### **Special care will be taken with Syner-KINASE if you:**

- have been recently bleeding from the stomach or intestines
- had surgery or have given birth recently
- have severe blood vessel disease in your brain
- have problems with your heart
- are elderly, particularly if you are aged over 75 years

In all these circumstances your doctor will decide whether or not you should be given Syner-KINASE.

**Taking or using other medicines:**

Please inform your doctor if you are taking, or have recently taken any of the following medicines, or any other medicines, including medicines obtained without a prescription:

- heparin or other anticoagulants
- acetylsalicylic acid (aspirin)
- non-steroidal anti-inflammatory agents
- dipyridamole
- dextrans

**Pregnancy and breast-feeding:**

Ask your doctor or pharmacist for advice before taking any medicine.

Syner-KINASE must not be used in pregnancy or immediately after delivery unless otherwise recommended by your doctor.

Do not breast-feed during treatment with Syner-KINASE.

**3. How Syner-KINASE is given:**

Syner-KINASE will be given to you by a doctor or nurse. You will not be asked to administer Syner-KINASE to yourself.

Before you are given Syner-KINASE it will be dissolved in saline (solution of salt and water). It should never be injected into a muscle or under the skin. The amount and duration of Syner-KINASE treatment will be decided by your doctor.

- if you are being treated for a blocked intravascular catheter or cannulae, Syner-KINASE may be injected directly into the catheter or cannulae and left for a while before removing the fluid. This may be repeated several times. Syner-KINASE may also be injected into the blocked tube over a period of time.
- if you are being treated for blood clots in your lungs, deep veins or peripheral arteries, Syner-KINASE may be injected into a vein (usually in the arm) or directly into the blocked vessel. Progress of the treatment may be checked by special X-rays. After the clot has been dissolved, you may be put on anticoagulant therapy (blood thinning) to prevent a recurrence.

**Use in children**

Syner-KINASE can be used in children to dissolve blood clots in intravenous catheters or cannulae.

#### **4. Possible side-effects:**

Like all medicines, Syner-KINASE can have side-effects but not everybody will get them.

#### **Tell your doctor immediately if you notice:**

- any bleeding
- any sign of an allergic reaction, such as difficulty with breathing, swelling of face, lips or throat, skin rash or hives

#### **Other side effects include:**

#### **Very common side effects (affects more than 1 user in 10)**

- unusual bleeding, particularly from puncture wounds or nose bleeds
- blood detected in the urine after a urine test
- blood clots: small fragments of a blood clot may be released and pass along the blood vessel and cause blockage elsewhere, such as in the lungs, heart or limbs
- a decrease in haematocrit (a red blood cell test) and a temporary increase in certain liver enzymes

#### **Common side effects (affects 1 to 10 users in 100)**

- bleeding in the stomach or into/around the brain or at puncture sites
- stroke
- tearing of an artery wall
- blockage of blood vessels due to cholesterol (fat)
- fever, chills and/or shivering

#### **Uncommon side effects (affects 1 to 10 users in 1000)**

- kidney failure

**Rare side effects (affects 1 to 10 users in 10,000)**

- visible blood in the urine
- injury and swelling in an artery wall

If you experience any of the above side effects, or if you notice anything else which is unusual, and not mentioned in this leaflet, please inform your doctor or pharmacist immediately.

**5. How to store Syner-KINASE:**

- keep out of the reach and sight of children
- do not store above 25°C
- do not keep reconstituted material for later use
- store in the original container and package in order to protect from light
- do not use after the expiry date stated on the label. The expiry date refers to the last day of the month
- do not use if the contents of the vial are discoloured
- medicines should not be disposed of via waste water or household waste

**6. Further information:**

The active ingredient is urokinase.

The other ingredients are: Mannitol, Disodium Edetate, Disodium Phosphate Dodecahydrate, Sodium Hydroxide.

**What Syner-KINASE looks like and contents of the pack:**

Each pack contains one vial (small bottle). The white powder contents are Syner-KINASE.

There are different strengths available:

Syner-KINASE® 10,000 IU

Syner-KINASE® 25,000 IU

Syner-KINASE® 100,000 IU

Syner-KINASE® 250,000 IU

Syner-KINASE® 500,000 IU

**Marketing Authorisation Holder (MAH)**

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