Package leaflet: Information for the user

Syner-KINASE® 10,000 IU powder for solution for injection/infusion
Syner-KINASE® 25,000 IU powder for solution for injection/infusion
Syner-KINASE® 100,000 IU powder for solution for injection/infusion
Syner-KINASE® 250,000 IU powder for solution for injection/infusion
Syner-KINASE® 500,000 IU powder for solution for injection/infusion

urokinase

Read all of this leaflet carefully before you start using 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 pharmacist.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

The name of your medicine is Syner-KINASE. The active ingredient is urokinase, an enzyme extracted from human urine which acts as a thrombolytic. This means it 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. What you need to know before you use Syner-KINASE

Syner-KINASE will not be given to you if you:
- are allergic (hypersensitive) to urokinase or any of the other ingredients of this medicine (listed in section 6)
- are currently bleeding or have been recently bleeding from the stomach or intestines
- have any cancer that has a risk of bleeding
- had a major surgical operation or a stroke recently
- had a recent trauma including cardiopulmonary resuscitation, chest or brain surgery (for example in the past 2 months)
- have severe high blood pressure
- have abnormal blood clotting or very low level of blood platelets
- have malformation of a blood vessel, for example a bulge
- have infection of the pancreas or heart, or any other severe infection
- have severely impaired liver or kidney function
- have given birth recently.

Warnings and precautions

Due to increased risk of bleeding, special care will be taken with Syner-KINASE if you:
- have severe blood vessel disease, especially in your brain
- have high risk of blood clots in your heart cavity, for example in case of abnormal heart rhythm (atrial fibrillation)
- have blood clotting abnormalities including those due to severe kidney or liver disease
- have cavities in your lungs
- have problems with your urinary tract that could result in bleeding (for example a bladder catheter)
- have blocked and infected blood vessels
- 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.

If severe bleeding occurs during treatment, Syner-KINASE will be stopped and medications to control the bleeding will be administered.

Syner-KINASE is made from human urine and certain measures are put in place to prevent infections being passed on to patients. However, despite these measures, when medicines prepared from human urine are administered, the possibility of passing on infection cannot be totally excluded.

Other medicines and Syner-KINASE
Please inform your doctor if you are taking, or have recently taken any of the following medicines as the possibility of bleeding can be increased by agents that counteract the clotting of blood, such as:
- heparin or other anticoagulants (blood thinning medicines)
- acetylsalicylic acid (aspirin), non-steroidal anti-inflammatory agents
- dipyridamole, dextrans (used to treat decreased volume of circulating blood plasma).

Please inform your doctor if you are taking an angiotensin converting enzyme (ACE) inhibitor (used to treat high blood pressure) as it may increase the possibility of an allergic reaction.

Tell your doctor if you are using, have recently used or might use any other medicines.

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

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 for advice before taking this 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.

Syner-KINASE contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

3. How to use Syner-KINASE

Syner-KINASE will be given to you by a doctor or nurse.

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
Urokinase concentration of 5,000 to 25,000 units dissolved in the volume of solvent required may be injected directly into the catheter or cannulae and left for 20-60 minutes before removing the fluid. This may be repeated several times if necessary. Syner-KINASE up to 250,000 units using a solution of 1,000 to 2,500 units per ml may also be infused into the blocked tube over a period of 90 to 180 minutes.

Blood clots that block the deep veins in the limbs
Initially, you may be given 4,400 units of urokinase per kg of your body weight in 15ml of solvent injected in a vein over a 10-minute period. This will be followed by 4,400 IU/kg/hour for 12-24 hours.

Blood clots that block vessels in your lungs
Initially, you may be given 4,400 units of urokinase per kg of your body weight in 15ml of solvent injected in a vein over a 10-minute period. This will be followed by 4,400 IU/kg/hour for 12 hours. Your doctor may decide instead to give you up to 3 injections into the lung artery at 24-hour intervals.

Blood clots that block an artery
Initially you may be given a solution of 2,000 units per ml directly into the clot at a rate of 4000 units per minute for 2 hours. Your doctor will check the blockage and may consider repeating this treatment up to 4 times until dissolution of the clot.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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
- collapse (fall in blood pressure) or turning blue (cyanosis)

Some patients may experience a sensation of warmth or cold (fever or chills), nausea and vomiting (feeling or being sick), back pain or shortness of breath within one hour of starting the infusion.

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, in the urine, into the muscles
- 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
- bleeding into the liver

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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Syner-KINASE

Keep this medicine out of the sight and reach 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 this medicine after the expiry date (i.e. EXP) which is stated on the label. The expiry date refers to the last day of that month.

Do not use this medicine if you notice discoloration of the contents.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Syner-KINASE contains

- The active substance 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 and Manufacturer

Marketing Authorisation Holder (MAH)

Syner-Medica Ltd
Syner-Med House
120 High Street
Purley
Surrey
CR8 2AD
United Kingdom

Manufacturers
Sirton Pharmaceuticals SpA
Piazza XX Settembre, 2
22079 Villa Guardia (CO)
Italy

GiPharma SRL
Via Crescentino
13040 Saluggia (VC)
Italy

Lyocontract GmbH (Only 100,000 IU, 250,000 IU and 500,000 IU.)
Pulverwiese 1
38871 Ilsenburg
Germany

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