PATIENT INFORMATION LEAFLET

Streptokinase Karma 250 000 and 750 000

Powder for solution for infusion

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 possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET?

1. WHAT STREPTOKINASE KARMA IS AND WHAT IT IS USED FOR.

Streptokinase Karma contains a number of ingredients. The active substance is a protein called streptokinase, an antithrombotic agent which dissolves blood clots.
You are being treated with Streptokinase Karma to break down blood clots in blood vessels.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN STREPTOKINASE KARMA.

You should not be treated with Streptokinase Karma if you:
- are allergic to streptokinase or any of the other ingredients in this medicine (listed in section 6)
- are pregnant
- are suffering from or have recently had internal bleeding
- have recently suffered a stroke or a serious head injury
- have recently had surgery, especially on your head (intracranial) or spine (intraspinal)
- have a brain tumour or a tumour with a risk of bleeding
- have uncontrollable high blood pressure
- have problems with your blood vessels (e.g. weakness in an artery)
- have a clotting disorder or are taking drugs to prevent blood clotting (anticoagulants)
- have an unusual susceptibility to bleeding
- have inflammation of the pancreas (acute pancreatitis) or inflammation in or around your heart (endocarditis or pericarditis)
- have severe liver or kidney damage.

WARNINGS AND PRECAUTIONS

Talk to your doctor or nurse before you are given Streptokinase Karma if you:
- have recently had severe bleeding in your stomach (e.g. an ulcer) or any other stomach or intestinal disorder that causes bleeding
- have recently had a severe injury and have been resuscitated
- are at risk of severe local bleeding for example if you have recently had an invasive operation (e.g. where you have had a tube or drip inserted into your body)
- have recently given birth or had a miscarriage or an abortion
- have any problems in the genital area or urinary tract, especially those with bleeding
- have had blood poisoning that could cause clotting (septic thrombotic disease)
- have a disease of the arteries or a disease affecting the blood vessels of your brain (cerebrovascular disease)
- have tuberculosis or similar lung diseases or severe bronchitis
- have any heart or circulation problems or high blood pressure
- have received any drug containing streptokinase or have had an infection caused by streptococcal bacteria such as rheumatic fever or a throat infection
- have damage to the eye caused by diabetes

CHILDREN

It is not recommended to use Streptokinase Karma in children, infants and neonates.

OTHER MEDICINES AND STREPTOKINASE KARMA

Tell your doctor or nurse if you are taking or have recently taken any other medicines, including those obtained without a prescription.
In particular tell the doctor or nurse if you have been treated with any drugs that prevent blood clotting (anticoagulants). Examples of such drugs are heparins, coumarin derivatives, dipyridamole and dextrans.

PREGNANCY AND BREAST-FEEDING

You should not be given Streptokinase Karma if you are pregnant or have recently had a baby, miscarriage or abortion unless there is no other, safer treatment.
You should not breastfeed your child while you are being treated with Streptokinase Karma.
Breast milk should be thrown away if you have been given streptokinase within the last 24 hours.

3. HOW STREPTOKINASE KARMA IS GIVEN TO YOU.

Streptokinase Karma will be given to you by a doctor or nurse. Your doctor will decide how much will be given and for how long.
- It will usually be infused into one of your veins with a drip.
- It may also be infused by a drip into an artery supplying blood to a limb, for example.
- If you have been treated with streptokinase before or have had a recent infection with the streptococcus bacteria (usually a throat infection), you may have high levels of antibodies against the active ingredient, streptokinase. These antibodies will block the action of streptokinase in your body, so your doctor may choose to use a different type of fibrinolytic agent.

IF YOU ARE GIVEN MORE STREPTOKINASE KARMA THAN YOU SHOULD HAVE BEEN

If this medicine is given for too long, bleeding problems may occur. You may be at risk of another blood clot (thrombosis). The symptoms are listed in section 4 under possible side effects.
Tell your doctor or nurse if you think you have been given too much.

4. POSSIBLE SIDE EFFECTS.

Like all medicines, Streptokinase Karma can cause side effects, although not everybody gets them.

IMMEDIATELY REPORT ALLERGIC REACTIONS such as skin rash, flushing, itching, blistering, swelling (may also affect the tongue or throat), or shortness of breath, low blood pressure (may feel light headed) to your doctor or nurse.

IF YOU RECEIVE A LOT OF STREPTOKINASE, YOU MAY BE AT RISK OF A BLOOD CLOT (THROMBOSIS).

Symptoms of a blood clot include:
- unusual pain or swelling in your legs
- sudden sharp pain in your chest
- sudden difficulty breathing
- an unusual, severe, or long-lasting headache
- dizziness or fainting.

THE FOLLOWING INFORMATION IS INTENDED FOR THE HEALTHCARE PROFESSIONALS ONLY.

Streptokinase Karma 250 000 and 750 000 Powder for solution for infusion

This is an extract from the Summary of Product Characteristics to assist in the administration of Streptokinase Karma 250 000 and 750 000. When determining appropriateness of use in a particular patient, the prescriber should be familiar with the Summary of Product Characteristics for the product.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Streptokinase Karma 250 000 and 750 000 are presented as powder for solution in vials containing 250 000 and 750 000 International Units (IU) of purified streptokinase as the active ingredient.

POSOLOGY AND METHOD OF ADMINISTRATION

This product is for use in adults. The safety and efficacy of Streptokinase Karma in children, infants and neonates have not been sufficiently established. The benefit of treatment has to be evaluated against the potential risks, which may aggravate an acute life-threatening condition.

METHOD OF ADMINISTRATION

The administration of streptokinase may be by systemic intravenous infusion or by local intra-arterial catheterdirected infusion.

The contents should be dissolved in 4-5 ml of physiological saline or water for injection. The solution should be swirled gently to facilitate quick reconstitution, but care should be taken to avoid foaming.

Physiological saline, 5% glucose solution, 5% fructose solution, or Ringer-lactate solution can be used as a diluent for administration with an infusion pump. Upon reconstitution with physiological saline a clear solution, colourless to yellowish, is obtained.

Note: When thrombolytic therapy is necessary and a high antibody concentration against streptokinase is present or when recent streptokinase therapy has been given (more than 5 days and less than one year previously), homologous fibrinolytics should be used.

ADULTS

Deep vein thrombosis
An initial dose of 250 000 IU streptokinase should be infused into a peripheral vein over 30 minutes. A maintenance infusion of 100 000 IU/hour for 72 hours should follow.

PULMONARY EMBOLISM

Infuse 1 500 000 IU streptokinase into a peripheral vein preferably over a short time of 1-2 hours.
As an alternative, an initial dose of 250 000 IU streptokinase should be infused into a peripheral vein over 30 minutes. A maintenance infusion of 100 000 IU/hour for 24 hours should follow.

OCCLUSIVE PERIPHERAL ARTERIAL DISEASES

Administer streptokinase with a local intra- arterial catheter-directed infusion using one of the following regimes:
- Gradual infusion: 1000 to 2500 IU streptokinase at an interval of 3 to 5 minutes for a maximum of 10 hours and a total maximum dose of 250 000 IU - Prolonged continuous low-dose infusion (using an infusion pump): 5000 to 10,000 IU streptokinase per hour for up to 5 days maximum.

A percutaneous transluminal angioplasty can be performed simultaneously, if necessary.

As an alternative for difficult arterial access or multiple occlusions, an initial dose of 250 000 IU streptokinase should be infused over 30 minutes. A maintenance infusion of 100 000 IU/hour for a maximum of 5 days should follow.

CENTRAL RETINAL VESSEL OCCLUSION

An initial dose of 250 000 IU streptokinase should be infused into a peripheral vein over 30 minutes.
A maintenance infusion of 100 000 IU/hour for 12 hours should follow.

CONTROL OF THERAPY

Before commencing thrombolytic therapy, it is desirable to obtain a thrombin time (TT), activated partial thromboplastin time (aPTT), haematocrit and platelet count to obtain the haemostatic status of the patient.

If heparin has been given it should be discontinued, and the TT or aPTT should be less than twice the normal control value before the thrombolytic therapy is started.

In patients previously treated with coumarin derivatives, the INR (international normalised ratio) should be below 1.3 before starting therapy with streptokinase.

SYSTEMIC ADMINISTRATION
During the infusion, decreases in the plasminogen and fibrinogen levels and an increase in the level of fibrin degradation product (FDP) (the latter two serving to prolong the clotting time of coagulation tests) will generally confirm the existence of a thrombolytic state.
Therefore, therapy can be monitored by performing the TT or aPTT approximately 4 hours after initiation of therapy.

A 2 to 4-fold prolongation of the TT should be aimed for and is considered a sufficient anticoagulation protection. If the thrombin time or any other parameter of lysis after 4 hours of therapy is less than approximately 1.5 times the normal control value, discontinue Streptokinase Karma as excessive resistance to streptokinase is present.

LOCAL ADMINISTRATION
As is usual with angiographies, heparin is administered, if necessary, prior to the angiography as a safeguard against catheter- induced thromboses.
The success of therapy can be determined by the angiography. With a sufficient blood flow of more than 15 minutes the therapy can be considered successful and then stopped.

FOLLOW-UP TREATMENT
After every course of streptokinase therapy, follow-up treatment with anticoagulants or platelet aggregation inhibitors can be instituted as prevention of rethromboses. With heparin therapy, in particularly, an increased risk of haemorrhage must be considered.

Infusion rate and corticosteroid prophylaxis
At the beginning of therapy, a fall in blood pressure, tachycardia or bradycardia (in individual cases going as far as shock) are commonly observed. Therefore, at the beginning of therapy the infusion should be performed slowly.

Corticosteroids can be administered prophylactically to reduce the likelihood of infusion-related allergic reactions.

PRE-TREATMENT WITH HEPARIN OR COUMARIN DERIVATIVES
If the patient is under active heparinization, it should be neutralised by administering protamine sulphate before the start of the thrombolytic therapy.
The thrombin time should not be more than twice the normal control value before thrombolytic therapy is started. In patients previously treated with coumarin derivatives, the INR (International Normalized Ratio) must be less than 1.3 before starting the streptokinase infusion.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
There is an increased risk of haemorrhage in patients who are receiving or who have recently been treated with anticoagulants,
e.g. heparin or drugs which inhibit platelet formation or function, e.g. platelet aggregation inhibitors, dextrans.
The effects of drugs which act upon platelet formation or function should be allowed to subside before starting long-term lysis of deep vein thromboses and arterial occlusions with streptokinase.

PHARMACEUTICAL INFORMATION
Excipients: Human albumin, Aminoacetic acid (glycine), Mannitol

Incompatibilities: No incompatibilities have been reported when Streptokinase Karma is used as recommended.
This medicinal product must not be mixed with other medicinal products.

Do not store the reconstituted solution for more than 24 hours in a refrigerator at +2°C to +8°C.

IF YOU EXPERIENCE ANY OF THESE SIDE EFFECTS TELL YOUR DOCTOR OR NURSE IMMEDIATELY.

VERY COMMON SIDE EFFECTS
(may affect more than 1 in 10 people)
- development of antibodies (proteins in the blood that help fight disease) against the active ingredient streptokinase

COMMON SIDE EFFECTS
(may affect up to 1 in 10 people)
- bleeding, especially at the injection site, bruising of the skin, bleeding into the stomach, reproductive and urinary systems, nosebleed
- slow or fast heartbeat
- feeling or being sick, diarrhoea, stomach pain
- headache, muscle pain including back pain, fever, chills, weakness, generally feeling unwell

UNCOMMON SIDE EFFECTS
(may affect up to 1 in 100 people)
- bleeding into eyes, liver, abdomen or joints, tearing of the spleen
- stroke (cerebrovascular haemorrhage)

RARE SIDE EFFECTS
(may affect up to 1 in 1,000 people)
- dizziness, confusion, agitation
- seizures
- weakness or paralysis on one or both sides of the body

VERY RARE SIDE EFFECTS
(may affect up to 1 in 10,000 people)
- bleeding into the space around the heart, including tearing of the heart muscle
- delayed allergic reactions, e.g. serum sickness (pain and swelling in joints and lymph nodes, rash, fall in blood pressure and shock), arthritis, inflammation of blood vessels and kidneys, numbness or pins and needles feeling in arms or legs
- blockage of blood vessels caused by cholesterol crystals
- fluid in the lungs (not caused by heart failure)
- inflammation in the eyes

The following events have been reported in patients being treated with streptokinase, but they may not have been caused by the medicine: irregular heartbeat, chest pain, lack of oxygen to the heart, heart failure, heart attack, heart shock, inflammation around the heart, fluid around the heart, stopping of heartbeat, heart valve insufficiency, blockage of a blood vessel.

REPORTING OF SIDE EFFECTS
If you get any side effects, talk to your doctor or nurse immediately. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 STREPTOKINASE KARMA IS STORED.
Your medicine will be given to you by your doctor. Normally, you will not need to store this medicine.
Keep this medicine out of the sight and reach of children.
Do not store above +25°C. Do not freeze. After the injection has been prepared it may be kept in a fridge at +2°C to +8°C for up to 24 hours.
Do not use this medicine after the expiry date.

6. CONTENTS OF THE PACK AND FURTHER INFORMATION.

What Streptokinase Karma contains.
- The active substance is streptokinase 250 000 IU or 750 000 IU (International Units).
- The other ingredients are human albumin, glycine and mannitol.

WHAT STREPTOKINASE KARMA LOOKS LIKE AND CONTENTS OF THE PACK
The medicine comes in glass vials as a white to slightly yellow powder. It is mixed with a liquid to make a solution to be used for infusion.
Each pack contains one vial with 250 000 IU or 750 000 IU of streptokinase.

MARKETING AUTHORISATION HOLDER
Karma Pharmatech GmbH
Emil-von-Behring-Str. 76
35041 Marburg, Germany
Tel: +49 (0) 6421 395811
Email: info@karma-pharmatech.com

MANUFACTURER
Karma Pharmatech GmbH
Emil-von-Behring-Straße 76
35041 Marburg, Germany
Fax: +49 (0) 6421 395812
Email: info@karma-pharmatech.com

FOR ANY INFORMATION ABOUT THIS MEDICINE, PLEASE CONTACT OUR LOCAL DISTRIBUTOR:
Aspire Pharma Limited
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
United Kingdom
Hampshire
GU32 3QG
Email: medinfo@aspirepharma.co.uk

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