What you should know about Biofactor Streptokinase

Help your doctor to help you.
Please read this leaflet carefully before you receive Biofactor Streptokinase. This leaflet contains important information. It also contains a number of questions about your medical history that will enable your doctor to treat you successfully. Since Biofactor Streptokinase is often used in emergency situations, it may not always be possible for you to read this leaflet before treatment. If you have already been treated with this medicine, please read this leaflet now because a lot of the information will still apply to you.

What is Biofactor Streptokinase and why are you receiving it?
Biofactor Streptokinase contains a number of ingredients. The active substance is a protein called streptokinase, which dissolves blood clots. Biofactor Streptokinase is available in three strengths, containing 100 000, 250 000 or 750 000 International Units of streptokinase.
Your medicine also contains human albumin, glycine and mannitol.
You are being treated with Biofactor Streptokinase because you are suffering from one of the following illnesses: pulmonary embolism, arterial thrombosis, deep venous thrombosis or retinal vessel thrombosis. These illnesses are all caused by a blood clot which has been formed inside one of your blood vessels. Biofactor Streptokinase is being given to you to break down the blood clot.

When should you not be treated with Biofactor Streptokinase?
Please answer the following questions.
- Are you sensitive or allergic to streptokinase?
- Have you received any drug containing streptokinase over the last 12 months or suffered an infection, such as rheumatic fever, caused by bacteria which produce streptokinase (streptococcal bacteria)?
- Are you suffering from internal bleeding?
- Have you recently suffered a stroke?
- Have you recently had an operation, in particular on the brain or the spine?
- Are you suffering from a cranial tumor?
- Do you have any heart or circulatory problems, or are you suffering from very high blood pressure that is no longer responding to treatment?
- Do you have a clotting disorder?
- Are you suffering from stomach or intestinal disorders which cause bleeding?
- Have you recently been given any type of injection?
- Have you recently been on a drip or artificially respirated?
- Have you recently been badly injured?
- Have you recently given birth or had an abortion?
- Do you have any problems in the genital or urinary tract which cause bleeding?
- Do you have kidney problems?
- Are you suffering from tuberculosis or similar lung diseases, or from severe bronchitis?
- Do you have any problems with the pancreas (acute pancreatitis)?
- Are you suffering from blood poisoning?
- Are you pregnant or breast feeding?
If you answered YES to any of the above questions, you should not be treated with Biofactor Streptokinase. Please tell your doctor immediately.

What precautions should be taken before you are treated with Biofactor Streptokinase?
In some cases, it may not be advisable for you to be treated with Biofactor Streptokinase, but your doctor may decide that treatment is essential. Please answer the following questions.
- Are you suffering from irregular heart beat or do you have problems with the heart valves?
- Are you suffering from loss of vision or eye discomfort?
- Are you suffering from deep vein thrombosis which is older than 14 days?
- Are you suffering from central retinal artery thrombosis which is older than 6 to 8 hours?
- Are you suffering from central retinal vein thrombosis which is older than 10 days?
If you answered YES to any of the above questions, or if you are unsure, please tell your doctor immediately. He will then discuss the risks and benefits of receiving Biofactor Streptokinase.

Is it safe for Biofactor Streptokinase to be given to pregnant and breastfeeding women?
If you are pregnant or breastfeeding, please tell your doctor. Biofactor Streptokinase should not be given to pregnant women unless there is no other, safer treatment. You should not breastfeed your child while you are being treated with Biofactor Streptokinase.

Is it safe for Biofactor Streptokinase to be given to children?
If Biofactor Streptokinase is to be given to children, a streptokinase resistance test should be performed before treatment. This test will enable the doctor to decide whether it is safe for the child to be treated with Biofactor Streptokinase and which dose should be used.

Is it safe to take other medicines while you are being treated with Biofactor Streptokinase?
If you are being treated, or have recently been treated, with any other medicine, please tell your doctor. This is particularly important if you have been given a drug that reduces the clotting activity of the blood. Examples of such drugs are heparins, coumarin derivatives, diprydiamole and dextran. In these cases, your doctor will take steps to neutralize the effects of the other drugs before you receive Biofactor Streptokinase.
How will you be treated with Biofactor Streptokinase?
Biofactor Streptokinase will be given to you by a doctor or nurse. It will be infused into one of your veins.

The dose will be chosen by your doctor to suit your individual case. Usually, two doses are given. The first (called loading) dose is intended to neutralize any streptokinase antibodies in your blood and the second (called maintenance) dose is intended to dissolve the blood clot.

The loading dose is usually infused for 30 minutes. Generally, the maintenance dose is infused for 72 hours for the treatment of deep vein thrombosis, for 24 hours for the treatment of pulmonary embolism, for 24 to 72 hours for the treatment of arterial thrombosis, and for up to 12 hours for the treatment of central retinal vessel thrombosis.

Before, during and after treatment with Biofactor Streptokinase, tests will be performed to measure the clotting activity of your blood. These tests will enable the doctor to decide when treatment should be started and when it can be stopped after successful breakdown of the clot. After successful treatment with Biofactor Streptokinase, you will probably be given an intravenous infusion of heparin to prevent new blood clots from being formed.

Can you be given too much Biofactor Streptokinase?
Your doctor will ensure that you are given the correct dose of Biofactor Streptokinase and that it will only be given for as long as necessary to achieve successful treatment. If this medicine is given for too long, bleeding problems may occur that will require medical attention.

What side effects may Biofactor Streptokinase have?
Medicines like Biofactor Streptokinase can cause side effects. Some of the side effects will disappear without treatment, but others may need medical attention. Tell your doctor or nurse immediately if you notice any of the following effects.

- **Bleeding**
  - You may notice slight bleeding, especially at sites where the skin has been punctured by an injection needle. Such bleeding can be quickly stopped.
  - Severe bleeding may occur but is very rare. If necessary, the infusion will be immediately stopped and appropriate countermeasures taken.

- **Early Reactions**
  - At the beginning of treatment, you may experience fever, chills, headache, stomach and intestinal upsets or pain in the muscles and bones. These effects can easily be treated by your doctor, and the symptoms disappear quickly.
  - A drop in blood pressure may occur but this effect usually disappears if the infusion rate is slowed. Changes in heart rate (fast or slow) have been observed occasionally.
  - Allergic reactions, such as rashes, flushing or shortness of breath, may occur. Such symptoms are a form of over-sensitivity and are usually caused by your medicine being infused too quickly. The symptoms usually do not last long and disappear when the infusion is stopped. If necessary, your doctor will take the appropriate countermeasures.
  - Lower back pain has been reported in some cases during treatment with streptokinase. Your doctor may decide to give you a painkiller.
  - Rarely, acute anaphylactic reactions (a very severe type of allergic response) have been observed. In such cases, infusion is immediately stopped and appropriate countermeasures are taken.

- **Other Reactions**
  - The following side effects have been seen on rare occasions during treatment with streptokinase.
    - Allergic responses in the brain and nerve tissues (neuroallergy)
    - Irritation of the eyes
    - Serum sickness
    - Fluid in the lungs
    - Increase in the levels of some enzymes and bilirubin (a bile pigment)
    - Jaundice may occur as a consequence of bilirubin increase.
    - Blockage of blood vessels by mobilized blood clots (embolism) that could cause pain or discomfort in the affected area. If this effect occurs in the lungs, streptokinase treatment will usually be continued as originally planned in order to dissolve the mobilized blood clots.

Most of these effects do not last long and disappear shortly after the infusion has stopped. The remaining effects can be treated by other medicines or therapy.

Like all medicines, Biofactor Streptokinase may have unwanted effects that are very rare. If you notice any undesirable effects not mentioned in this leaflet or any change in your health while receiving this medicine, or afterward, tell your doctor or nurse immediately.

Who makes Biofactor Streptokinase
The license holder for Biofactor Streptokinase is Biofactor GmbH, Bad Homburg, Germany.

When was this leaflet prepared?
This leaflet was compiled in December 1997 and updated in November 2006.

Please remember
This leaflet was written to inform you about Biofactor Streptokinase. It may not contain all you wish to know about your medicine. If you have further questions, or are not sure about something, please ask your doctor.