

PATIENT INFORMATION LEAFLET

Biofactor Streptokinase 1 500 000

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 Biofactor Streptokinase is and what it is used for.
2. What you need to know before you are given Biofactor Streptokinase.
3. How Biofactor Streptokinase is given to you.
4. Possible side effects.
5. How Biofactor Streptokinase is stored.
6. Contents of the pack and further information.

1. What Biofactor Streptokinase is and what it is used for.

Biofactor Streptokinase 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 Biofactor Streptokinase because you have suffered a recent heart attack, which was caused by a blood clot blocking the blood supply to your heart. Biofactor Streptokinase is being given to you to break down the blood clot.

2. What you need to know before you are given Biofactor Streptokinase.

You should not be treated with Biofactor Streptokinase 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 Biofactor Streptokinase if you:

- have recently had severe bleeding in your stomach (e.g. an ulcer) or an 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 Biofactor Streptokinase in children, infants and neonates.

Other medicines and Biofactor Streptokinase

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 Biofactor Streptokinase if you are pregnant.

You should not breastfeed your child while you are being treated with Biofactor Streptokinase. Breast milk should be thrown away if you have been given streptokinase within the last 24 hours.

3. How Biofactor Streptokinase is given to you.

Biofactor Streptokinase 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 be infused slowly into one of your veins with a drip.

It may also be infused by a drip into an artery supplying blood to your heart.

After treatment with streptokinase, your doctor may decide to give you aspirin for about four weeks to help thin your blood.

If you are given more Biofactor Streptokinase 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, Biofactor Streptokinase 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.

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 with heart attack 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How Biofactor Streptokinase 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 which is stated on the carton and vial label.

6. Contents of the pack and further information.

What Biofactor Streptokinase contains.

- The active substance is streptokinase 1 500 000 IU (International Units).
- The other ingredients are human albumin, glycine and mannitol.

What Biofactor Streptokinase 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 1 500 000 IU of streptokinase.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in 10/2014.