

STREPTASE(R)

(strep-tays)

streptokinase (strep-toe-kine-ays)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Streptase.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Streptase against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Streptase is used for

The active ingredient of Streptase is streptokinase, an enzyme produced by streptococcus bacteria. Streptase is used in hospitals to dissolve blood clots, especially those in the heart and lungs. It is also used on the clots formed in the tubing during kidney dialysis.

Your doctor may have prescribed Streptase for another reason.

Ask your doctor if you have any questions about why Streptase has been prescribed for you.

This medicine is available only with a doctor's prescription.

Streptase is not recommended for use in children.

Before you are given it

When you must not be given it

You must not receive Streptase if:

- * you have a severe allergy to Streptase or an allergy to any of the ingredients listed at the end of this leaflet
- * you are bleeding
- * you have received streptokinase more than 5 days ago and less than 12 months ago
- * any of the following apply to you:
 - recent haemorrhage, biopsy or surgery of any kind
 - peptic ulcer, ulcerative colitis (inflammation of the colon) or diverticulitis (inflammation in the colon)
 - stomach or head tumours or a tumour or cancer that may bleed
 - thrombocytopaenia (an abnormally low number of platelets in the blood)
 - any condition which reduces the clotting ability of your blood
 - liver or kidney disturbances
 - uncontrolled high blood pressure
 - pancreatitis (inflammation of the pancreas)

- heart conditions that may cause blocking of the heart's blood vessels such as bacterial endocarditis or pericarditis
- aneurysm or other malformation of a blood vessel
- streptococcal (bacterial) infections such as rheumatic fever

Your doctor, nurse and pharmacist will ensure that you are not given Streptase after the expiry date (EXP) printed on the pack.

If you are given this medicine after the expiry date has passed, it may not work as well.

Your doctor, nurse and pharmacist will ensure that you are not given Streptase if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start being given Streptase, contact your doctor.

Before you are given it

Tell your doctor, nurse or pharmacist if you have allergies to:

- * any other medicines
- * any other substances, such as foods, preservatives or dyes

Tell your doctor, nurse or pharmacist if you are pregnant or intend to become pregnant.

Your doctor or pharmacist will discuss the possible risks and benefits of using Streptase during pregnancy.

Tell your doctor, nurse or pharmacist if you are breastfeeding or plan to breastfeed.

Your doctor or pharmacist will discuss the possible risks and benefits of using Streptase during breast-feeding.

Tell your doctor or nurse if you have ever had streptokinase (Streptase) before.

Streptokinase causes the body to make antibodies against it. This is not harmful but may mean you need to be given a different medicine.

Tell your doctor, nurse or pharmacist if you have or have had any medical conditions, especially the following:

- * recent surgery or medical emergency
- * tumours or cancer
- * ulcers
- * liver or kidney disturbances
- * high blood pressure
- * pancreatitis (inflammation of the pancreas)
- * diabetes
- * heart or lung conditions
- * arthritis

If you have not told your doctor, nurse or pharmacist about any of the above, tell them before you start being given Streptase.

Taking other medicines

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Streptase may interfere with each other. These include:

- * drugs used to treat high blood pressure or angina (a heart condition that causes severe chest pain and breathlessness)
- * drugs used to increase or decrease the clotting of the blood such as tissue plasminogen activator, heparin, aspirin, dipyridamole

and dextrans

- * phenylbutazone and non-steroidal anti-inflammatory drugs. These drugs are used to treat a variety of conditions to reduce pain and inflammation (swelling, redness and soreness) such as arthritis, muscle and bone injuries, period pain, headache, or pain following surgery and dental procedures

These medicines may be affected by Streptase, or they may affect how well it works. You may need different amounts of your medicine, or you may need to receive different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while receiving Streptase.

How it is given

Streptase is injected or infused into a blood vessel. The way your doctor gives you Streptase and the dose will depend on the reason Streptase is being used.

While you are being given it

Things you must do

If you develop itching with swelling or skin rash, difficulty breathing, dizziness or abnormal heartbeats while you are receiving Streptase, tell your doctor or nurse immediately.

If you become pregnant while being treated with Streptase, tell your doctor or pharmacist.

Tell all the doctors, nurses, dentists and pharmacists who are treating you that you are being treated with Streptase.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while receiving Streptase.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need urgent treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse immediately if you notice any of the following:

- * bleeding.
- * red or itchy skin with swelling, skin rash or difficulty breathing.
- * chest pains
- * abnormal heart beats
- * seizures

Tell your doctor or nurse if you notice any of the following and they worry you:

- * dizziness
- * headache
- * fever
- * back or muscle pain
- * stomach disturbances
- * weakness or generally feeling unwell

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

After using STREPTASE

Storage

Streptase should be stored in the pharmacy or on the ward. The injection should be kept in a cool

**dry place, protected from light,
where the temperature stays below
25 degrees C.**

Product description

What it looks like

White powder for injection in a vial.

Ingredients

Active Ingredient:

250,000 IU, 750,000 IU or 1,500,000
IU streptokinase per vial

Inactive Ingredients:

- * polygeline
- * monosodium glutamate (MSG)
- * albumin.

Manufacturer/Distributor

Streptase is made in Germany.

Streptase is supplied in Australia by:
sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Streptase is supplied in New Zealand
by:
CSL Biotherapies (NZ) Ltd
666 Great South Road
Penrose, Auckland 6, New Zealand

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