

## New Zealand Consumer Medicine Information

### **Actilyse<sup>®</sup>**

#### ***Alteplase***

---

#### **What is in this leaflet**

---

This leaflet answers some common questions about Actilyse. It does not contain all available information. It does not take the place of talking to your doctor or pharmacist. Consider keeping this information even after your treatment is finished. You may want to read it again later.

#### ***To find out more about Actilyse***

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any concerns about being treated with Actilyse.

---

#### **What Actilyse is used for**

---

Actilyse is intended to be used either during the early stages of a heart attack or in a condition of the lungs known as acute massive pulmonary embolism. Actilyse is also used in the early treatment (within 3 hours of onset of symptoms) of a particular type of stroke known as acute ischaemic stroke. Acute ischaemic stroke occurs when a blood clot blocks a blood vessel in the brain. This leads to a sudden interruption of blood flow to an area of the brain, and results in damage of brain tissue.

Actilyse works by dissolving clots in the blood vessels. These clots cause disease by interfering with normal blood flow.

If you want more information about what Actilyse is used for, ask your doctor.

---

#### **Before being treated with Actilyse**

---

##### ***When Actilyse should not be used***

You should not be treated with Actilyse if you are allergic to it or to any of the ingredients. These ingredients are listed in full at the end of this leaflet. If you are uncertain as to whether you have such an allergy you should raise this concern with your doctor.

Because of the risk of bleeding, Actilyse should not be used if you have, or have had:

- current bleeding or severe bleeding in the past 6 months
- a family history of bleeding disorders
- a previous condition resulting in bleeding or suspected bleeding in the brain
- heart and lung resuscitation, childbirth, organ biopsy or an invasive medical procedure in the past 10 days
- major surgery, including heart, head or spinal surgery, or significant trauma (including trauma to the head) in the past 3 months
- a stroke due to bleeding in the brain or a stroke of unknown origin at any time (this only applies for treatment of heart attack or pulmonary embolism)

- a stroke caused by a blood clot or a transient ischaemic attack (TIA) in the past 6 months, except for current acute ischaemic stroke within the past 3 hours (this only applies for treatment of heart attack or pulmonary embolism)
- severe and uncontrolled high blood pressure
- tumours in which the risk of bleeding is increased
- any blood clotting defect
- current treatment with an anti-clotting agent (anticoagulant), such as warfarin
- certain diseases of the blood vessels, heart, brain, oesophagus, stomach/intestine, liver, kidney or pancreas in which the risk of bleeding is increased.

In addition to the above medical conditions, Actilyse should not be used for the treatment of acute ischaemic stroke if you have, or have had:

- any condition that increases the risk of bleeding in the brain
- fits or seizures at the onset of stroke
- treatment with heparin in the past 48 hours (and abnormal bleeding time)
- previous stroke or serious head injury/trauma within the last 3 months; or previous stroke with diabetes mellitus
- a low platelet count (platelets are blood cells involved in blood clotting)
- severe high blood pressure
- abnormal blood glucose levels.

If you are uncertain as to whether you have, or have had, any of these conditions (or medicines) you should raise those concerns with your doctor. Actilyse should not be used together with any other medicine which dissolves blood clots, such as streptokinase or urokinase.

Actilyse must not be used after the EXPIRY DATE on the carton or vial.

### ***Before treatment with Actilyse***

It is important that your doctor knows your medical history before administering Actilyse. Before being treated with Actilyse, your doctor should know if you have, or have had, any of the following conditions:

- a previous heart attack or any other heart condition
- a previous stroke caused by a blood clot or a transient ischaemic attack (TIA) more than 6 months previously (this only applies for treatment of heart attack or pulmonary embolism)
- diabetes mellitus
- bleeding from inside or around your eyes
- high blood pressure
- severe liver disease
- any recent medical procedure such as a biopsy or injection.

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

Before Actilyse is administered your doctor should know if you are using any other medicines, and if you have ever taken:

- aspirin, heparin, warfarin or any other agent which affects the ability of the blood to clot
- ACE inhibitors (a group of medicines used for treatment of high blood pressure).

In addition, before starting treatment your doctor will assess other factors which may increase the risks of using Actilyse. These include infected veins and cannula sites or any condition in which bleeding is a significant risk or would be particularly difficult to manage because of its location.

### ***Pregnancy***

The risks of treatment with Actilyse may be increased during pregnancy. You must tell your doctor if you are, or may be, pregnant. Actilyse should only be given to pregnant women if the need clearly outweighs the potential risk.

### ***Breastfeeding***

It is not known whether Actilyse enters the breast milk. Special care is recommended if you are breastfeeding and you should ask for your doctor's advice in this situation.

### ***Children***

There is not enough information available to recommend the use of Actilyse in children. Actilyse should not be used for treatment of acute ischaemic stroke in patients less than 18 years of age.

### ***Patients over 70 years***

The risks of treatment with Actilyse may be increased in patients over 70 years if they have, or have had, high blood pressure, or in any patient over 75 years of age. Actilyse should only be given to these patients if the need clearly outweighs the potential risk. Actilyse should not be used for treatment of acute ischaemic stroke in patients over 80 years of age.

---

## **Treatment with Actilyse**

---

Treatment with Actilyse should begin as soon as possible after the onset of symptoms.

### ***How Actilyse is used***

Actilyse is a powder which must be mixed with sterile water for injections before being given into a vein through a drip line. For the treatment of a heart attack, you may also receive other medications to help prevent the blood vessel(s) becoming blocked again after treatment.

For the treatment of pulmonary embolism, it is recommended that heparin be given soon after treatment with Actilyse but the two medicines must be given through separate drip lines.

However, in the treatment of acute ischaemic stroke, the administration of aspirin or heparin is not recommended within the first 24 hours after Actilyse treatment.

Actilyse should only be used under the supervision of a doctor and in a setting where appropriate equipment is readily available for diagnosis and patient monitoring.

### ***Recommended dose***

The recommended dose is 100 mg given over 90 or 180 minutes for a heart attack, or over 120 minutes for acute massive pulmonary embolism. A lower dose (1.5

mg/kg) is recommended for patients weighing less than 65 kg. No more than 100 mg should be given because it is associated with a higher risk of bleeding (especially in the brain).

For treatment of acute ischaemic stroke a dose equivalent to 0.9 mg/kg body weight is given over 60 minutes. The maximum dosage should not exceed 90 mg.

Your doctor might prescribe a different dose or duration of treatment to that described here. If you want more information, ask your doctor.

### **Overdose**

Overdose is unlikely because Actilyse is administered under medical supervision. If too much Actilyse is administered, the most likely effect is bleeding. In the case of serious bleeding, your doctor will immediately stop treatment with Actilyse and heparin. Your doctor will start appropriate treatment to control the bleeding and, if necessary, replace the lost blood.

---

### **Side effects**

---

You should be aware that all prescription medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Your doctor has weighed the risks of using Actilyse against the benefits they expect it will have for you. Ask for the advice of your doctor or other medical staff if you have any concerns about the effects of being treated with this medicine.

The most common side effect is bleeding. This may have an effect on your blood readings. Bleeding may be obvious if it is from the skin, gums or nose. A more serious situation is when bleeding occurs inside the body (internally), for example, bruising and stroke (bleeding in the brain). Other symptoms such as drowsiness, difficulty speaking, inability to move parts of your body and convulsion may also occur if you experience bleeding in the brain.

Internal bleeding can occur at any site or body cavity and may result in life-threatening situations, permanent disability or death.

Due to the life-threatening nature of the diseases for which Actilyse is used, some deaths have occurred after treatment. However, use of Actilyse in large numbers of patients has shown that when used as recommended, the benefits outweigh the risks.

Actilyse may cause allergic reactions but this is not common. Mild allergic reactions such as itchy skin rash have been observed. Serious or life-threatening allergic reactions, perhaps causing low blood pressure and difficulty breathing, are rare. There have also been reports of blockages of blood vessels following treatment with Actilyse. This can lead to organ failure (e.g. kidney failure). These serious effects are rare.

Other side effects include nausea, vomiting, low blood pressure, irregular heart beat and fever. These events commonly occur after a heart attack and may or may not be increased by Actilyse.

Tell your doctor as soon as possible if you experience any side effects during or after treatment with Actilyse, so that these may be properly treated. In addition,

unexpected effects, not listed above, can occur with any medicine. You should tell your doctor if you notice anything unusual, during or after treatment with Actilyse.

---

## **After treatment with Actilyse**

---

Actilyse increases the risk of bleeding and bruising. After treatment with Actilyse medical staff will avoid giving you injections or moving you unless absolutely necessary. Your doctor will probably continue to treat you with heparin and aspirin after treatment with Actilyse. This is to reduce the risk of more blood clots forming.

Actilyse powder must be stored below 30°C and protected from light. After mixing with sterile water for injections, Actilyse can be kept for up to 24 hours in a refrigerator (2-8°C). It is for single use only and any unused solution must be discarded.

---

## **Product Description**

---

### ***What the product looks like***

Actilyse is the brand name of the medicine prescribed for you by your doctor. It comes as a sterile white to off-white powder in clear glass vials containing 10 mg or 50 mg alteplase.

Actilyse powder must be mixed with sterile water for injections before use. When mixed, the resulting solution is colourless to pale yellow.

Actilyse is sold as a pack containing one vial of powder and one vial of sterile water for injections.

### ***Ingredients***

Each vial of Actilyse powder contains 10 mg or 50 mg of alteplase. The powder also contains:

- L-arginine
- phosphoric acid
- and polysorbate 80.

Sodium hydroxide or phosphoric acid may be added to adjust the acidity of Actilyse.

A 10 ml or 50 ml vial of sterile Water for Injections is provided for mixing with the powder.

### ***Manufacturer***

Actilyse is made in Germany and supplied in New Zealand by:  
BOEHRINGER INGELHEIM (N.Z.) Limited  
PO Box 76-216  
Manukau City  
Auckland  
Ph 0800 802461

This leaflet was prepared on 19 September 2008  
© Boehringer Ingelheim 2008