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EPAR summary for the public

Rapilysin

reteplase

This is a summary of the European public assessment report (EPAR) for Rapilysin. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Rapilysin.

What is Rapilysin?

Rapilysin is a powder and solvent that are made up into a solution for injection. It contains the active substance reteplase.

What is Rapilysin used for?

Rapilysin is used within 12 hours of a suspected heart attack to help dissolve the blood clots obstructing the flow of blood to the heart muscle.

The medicine can only be obtained with a prescription.

How is Rapilysin used?

Rapilysin should be prescribed by doctors who have experience in using medicines that dissolve blood clots and who can monitor its use.

Treatment with Rapilysin should be started as soon as possible after the start of heart attack symptoms. Rapilysin is given as two injections, 30 minutes apart. Each injection is given into a vein slowly, but in less than two minutes. Other medicines that prevent clotting (aspirin and heparin) should be given before and after the Rapilysin injection to stop clots from forming again. However, Rapilysin and heparin or aspirin must not be given in the same syringe.

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How does Rapilysin work?

The active substance in Rapilysin, reteplase, is a copy of a natural enzyme called t-PA that has been modified so that it starts working faster and for longer. Reteplase activates the production of an enzyme called plasmin, which breaks up blood clots. Following a heart attack, Rapilysin can help dissolve blood clots that have formed in the arteries supplying the heart muscle, thereby restoring normal blood flow to the heart.

How has Rapilysin been studied?

Rapilysin has been studied in more than 21,000 patients in four studies. Rapilysin has been compared with other medicines used to dissolve blood clots: streptokinase in 6,000 patients and alteplase in about 15,000 patients. The studies looked at the number of patients who had died 30 to 35 days after treatment, and at the number of patients who had heart failure (an inability of the heart to pump enough blood around the body) or a stroke.

What benefit has Rapilysin shown during the studies?

Rapilysin was more effective than streptokinase in reducing the number of patients with heart failure, and it was as effective as streptokinase in preventing death. Rapilysin was also as effective as alteplase in preventing death and stroke.

What is the risk associated with Rapilysin?

The most common side effects with Rapilysin (seen in more than 1 patient in 10) are bleeding at the injection site, recurrent ischaemia (reduced blood supply to parts of the body) or angina (severe chest pain), hypotension (low blood pressure), heart failure or pulmonary oedema (build-up of fluid on the lungs), and reactions at the site of the injection, such as burning sensations. For the full list of all side effects reported with Rapilysin, see the package leaflet.

Rapilysin must also not be used in patients who are at risk of bleeding because of other diseases, treatment with other medicines, high blood pressure, previous bleeding or recent surgery. For the full list of restrictions, see the package leaflet.

Why has Rapilysin been approved?

The CHMP decided that Rapilysin's benefits are greater than its risks for and recommended that it be given marketing authorisation.

Other information about Rapilysin

The European Commission granted a marketing authorisation valid throughout the European Union for Rapilysin on 9 November 1996.

The full EPAR for Rapilysin can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Rapilysin, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2016.