PATIENT MEDICATION INFORMATION :

ACTIVASE® RT-PA (ACUTE ISCHEMIC STROKE)

alteplase
Fibrinolytic Agent
Roche

Date of Revision: May 1, 2018

IMPORTANT: PLEASE READ: This leaflet is part III of a three-part "Product Monograph" published when ACTIVASE rt-PA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ACTIVASE rt-PA. Contact your doctor or pharmacist if you have any questions about the drug.

About This Medication:

What the medication is used for:

ACTIVASE rt-PA is indicated for the management of acute ischemic stroke (AIS) in adults for improving neurological recovery and reducing the incidence of disability.

What it does:

ACTIVASE rt-PA, when introduced into the blood circulation, will bind to fibrin (protein that prevents the flow of blood) in blood clots and converts the entrapped plasminogen to plasmin (which breaks down fibrin clots).

When it should not be used:

If you have:

- Hypersensitivity to alteplase or to any ingredient in the formulation or components of the container
- Symptom onset greater than 3 hours
- Bleeding disorder or recent history of bleeding
- Recent major surgery or trauma
- Uncontrolled high blood pressure (e.g., >185 mm Hg systolic or >110 mm Hg diastolic)
- Treatment required to reduce blood pressure
- Seizure at the onset of stroke
- Brain tumour, abnormality of the blood vessels, or aneurysm
- Recent gastrointestinal or urinary tract bleeding
- Recent arterial puncture
- Abnormal blood glucose levels
- Recent heart attack or heart lining inflammation

Treatment of patients with problems with nerve, spinal cord or brain function or with rapidly improving symptoms is not recommended.

What the medicinal ingredient is:

Alteplase

What the important nonmedicinal ingredients are:

L-arginine, phosphoric acid and polysorbate 80

What dosage forms it comes in:

ACTIVASE rt-PA is available in:

1. Boxes each containing one (1) vial of ACTIVASE rt-PA 50 mg and one (1) vial of Sterile Water for Injection, USP 50 mL, for preparing a sterile solution of ACTIVASE rt-PA.
2. Boxes each containing one (1) vial of ACTIVASE rt-PA 100 mg and one (1) vial of Sterile Water for Injection, USP 100 mL, and one transfer device for preparing a sterile solution of ACTIVASE rt-PA

Warnings and Precautions:

Serious Warnings and Precautions

ACTIVASE rt-PA is a drug known to cause severe bleeding and an increased incidence of bleeding in the skull.

Use of ACTIVASE rt-PA for the treatment of stroke is limited to physicians experienced in acute stroke management, who are treating patients in a hospital setting.

The most common complication encountered during therapy with ACTIVASE rt-PA (alteplase for injection) is bleeding.

BEFORE ACTIVASE rt-PA is given, your doctor will review the possible risks based on your medical condition and history, including if you are/have/had:

- Severe problems with the nerve, spinal cord or brain function
- Major early infarct signs such as swelling, growing mass, or midline shift (detected through a CT scan)
- Recent major surgery or trauma
- Clinical evidence or history of transient ischemic attacks
- Recent gastrointestinal or urinary tract bleeding
- High blood pressure (i.e., ≥175 mm Hg systolic and/or ≥110 mm Hg diastolic)
- History or clinical evidence of high blood pressure in a patient over 70 years old
- Over 75 years old
- Problems with the heart or heartbeat
- Severe liver failure
- Pregnancy
- Serious infection or inflammation
- Taking medications that affect blood clotting (i.e., warfarin sodium)
- Use of blood dissolving drugs
- Cholesterol embolization
- Abnormal blood glucose levels

Interactions with This Medication:

Drugs that may interact with ACTIVASE rt-PA include:

- Anticoagulants such as heparin and warfarin
- Drugs that alter platelet function (such as acetylsalicylic acid)

- Angiotensin-converting enzyme (ACE) inhibitors

Proper Use of This Medication:

ACTIVASE rt-PA (alteplase for injection) is intended for intravenous use only.

Usual dose:

The recommended dose is 0.9 mg/kg (maximum of 90 mg) infused over 60-minutes with 10% of the total dose administered as an initial intravenous bolus over 1 minute. The recommended total dose is based upon patient weight.

Refer to Product Monograph Part I—Health Professional Information—Dosage and Administration section for additional Preparation and Administration information.

Overdose:

Overdosage could lead to serious bleeding.

Should serious bleeding occur in a critical location, the infusion of ACTIVASE rt-PA (alteplase for injection) and any other concomitant anticoagulant should be discontinued immediately. If necessary, blood loss and reversal of the bleeding tendency can be managed with whole blood or packed red cells.

In the event of clinically significant fibrinogen depletion, you may be infused with fresh frozen plasma or cryoprecipitate.

Side Effects and What to Do About Them:

Like all medicines, ACTIVASE rt-PA can have side effects. Below are some of the side effects associated with ACTIVASE rt-PA:

- Allergic-type reactions, e.g. anaphylactoid reaction, anaphylactic reaction, throat swelling, angioedema, rash, hives, shock
- Internal bleeding, involving the gastrointestinal and urinary tract, lungs, or within the skull
- Potential bleeding sites as a result of recent invasive procedure (i.e., catheter insertions, puncture, surgery)
- Swelling or high pressure in the brain, uncontrollable shaking (seizure), new ischemic stroke, embolism

For any unexpected effects while taking ACTIVASE rt-PA, contact your doctor or pharmacist.

In all cases, the health care professional will decide whether the drug should be stopped or not.

How to Store It:

Store between 2 and 30°C. Protect from excessive exposure to light.

Unused reconstituted ACTIVASE rt-PA (in the vial) may be stored at 2-30°C for up to 8 hours. After that time, any unused portion of the reconstituted material should be discarded.

During the period of reconstitution and infusion, protection from light is not necessary.

Reporting Suspected Side Effects

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You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

Note: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

More Information:

This document plus the full product monograph, prepared for health professionals can be found at:

http://www.rochecanada.com or by contacting the sponsor Hoffmann-La Roche Limited, at: 1-888-762-4388

This leaflet was prepared by Hoffmann-La Roche Limited