Alteplase (tPA) Thrombolysis for Acute Stroke Dosing Chart

Concentration: 1 mg/mL

**Admixture:**
Reconstitute 100 mg vial with 100 mL sterile water provided, see package insert for detailed instructions.
Withdraw bolus dose from vial. Infuse remainder of dose over 60 minutes.

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<th>Weight kg</th>
<th>First Over 1 minute</th>
<th>DOSE mg</th>
<th>RATE mL/hr</th>
<th>Next 60 minutes</th>
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Values have been rounded off
# Alteplase

## Other Names
- Tissue-type Plasminogen Activator (Recombinant) rt-PA, t-PA, ACTIVASE rt-PA, Cathflo®

## Classification
- Thrombolytic

*Elder Alert*
See Cautions

## Indications for IV Use
**Health Canada Approved:**
- Treatment of acute MI. **In SHR alteplase has been replaced with tenecteplase for this indication.**
- Treatment of acute ischemic stroke within 3 (to 4.5) hours from symptom onset.* (see non-approved indications below)
- For the restoration of function to central venous access devices

**Non-Approved Health Canada Indications but Substantiated in the Literature:**
- Treatment of acute ischemic stroke within 4.5 hours from symptom onset.\(^1\)
- Treatment of pulmonary embolism with severe hemodynamic compromise and/or severe hypoxemia.\(^2\)
- Catheter-directed thrombolysis after angiographic placement of catheter tip.\(^2,4\)
- Lysis of hemodialysis catheter-associated fibrin sheaths.\(^5-6\)

## Contraindications to Use in Acute Ischemic Stroke (per Activase® rt-PA Product Monograph)\(^13,14\)
- Refer to Appendix A in SHR Acute Stroke Thrombolytic (tPA) Administration Order Set for SHR inclusion/exclusion criteria\(^17\)
- Hypersensitivity to alteplase
- Time of onset of stroke greater than 3 hours. Do not administer alteplase in a minor, or rapidly resolving stroke.
- Evidence of an intracranial hemorrhage or suspicion of a subarachnoid hemorrhage; intracranial neoplasm, AV malformation or aneurysm
- Recent (within 3 months) stroke or serious head trauma; intracranial or intraspinal surgery
- Myocardial infarction in the previous 3 months and/or clinical presentation associated with post-MI pericarditis.
- Gastrointestinal or urinary tract hemorrhage in previous 21 days
- Major surgery in previous 14 days
- History of intracranial hemorrhage
- BP elevated (SBP >185 mm Hg and DBP > 110 mm Hg). Aggressive treatment required to reduce BP to specified limits.
- Seizure at the onset of stroke
- Active internal bleeding
- Known bleeding risk: current use of an oral anticoagulant (e.g. warfarin) or an INR greater than 1.7 or a PT greater than 15 secs; heparin in the previous 48 hours and an elevated aPTT on presentation; platelet count less than 100,000 mm\(^3\)
- Blood glucose less than 3 or greater than 22 mmol/L
- Arterial puncture at a noncompressible site within the previous 7 days

**Caution**\(^1\)
- Elderly: may have pre-existing conditions that may increase risk of intracranial bleeding.
- Avoid conditions in which bleeding constitutes a substantial hazard or would be difficult to control because of its location.
- Avoid any excessive or rough handling of patient; avoid invasive procedures (e.g. arterial puncture, venipuncture, IM injection). If these procedures are absolutely necessary, use extreme precautionary methods (use radial artery instead of femoral; use small-gauge catheters and needles, and sites that are easily observed and compressible where bleeding can be controlled; avoid handling catheter sites and use extended pressure application of up to 30 minutes).

## Drug Interactions
- Oral anticoagulant or heparin may increase risk of hemorrhage.
- Drugs that affect platelet function, such as ASA, NSAID’s, may increase risk of hemorrhage.

**Pregnancy/Breast Feeding:** Contact Pharmacy for most recent information

## Administration

### Requirements
- IV infusion device and a vented administration set if infusing directly from glass bottle

### Monitoring
* To be administered (except Bolus dose) and monitored by Critical Care Personnel

**Continuous infusion:**
- Add 50 mg to 500 – 1000 mL NS for 0.1 – 0.05 mg/mL \(^4,8\)
- Catheter-directed thrombolysis:

### Intermittent Infusion
- Further dilution not required.
- **Ischemic stroke:** Infuse over 1 hour\(^12\)
- **Pulmonary embolism:** Infuse over 2 hours.\(^2\)

### Bolus Dose
- Ischemic stroke: over 1 minute administered by physician\(^12\)

### Continuous Infusion
- Continuous cardiac monitoring (see Appendix A) for a minimum of 2 hours.
- Baseline T, BP, HR and neurological assessment, then q 15 minutes for the first 2 hours after drug initiated; then q 30 minutes and PRN for 2 hours; then q4h and PRN.
- Visual assessment for signs and symptoms of bleeding q 30 min during infusion, then q1 h x 6, then q4 h x 48 hours.
- Assess for frank or occult blood in stool, emesis, sputum and urine for at least 72 hours after initiation of therapy.

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**Continued...**
Continuous infusion:
- Visual assessment for signs and symptoms of bleeding q 30 min during infusion, then q1h x 6. If on concomitant heparin continue q 2h x 3 then stop i.e. monitor for 12 hours after infusion stops if on concomitant heparin.
- Baseline BP, HR and neurological assessment, then q1 h during infusion and for 6 hours after. If on concomitant heparin continue q2h x 3 then stop.
- Assess for frank or occult blood in stool, emesis, sputum and urine for at least 72 hours after initiation of therapy.

Baseline PT-INR, PTT, CBC with platelet count, fibrinogen, hematocrit, thrombin time and repeat daily during infusion.

For neurological changes, e.g. headache, visual changes.

See package insert for reconstitution instructions. Do not shake the vial. Swirl and/or invert gently to mix.

Available as alteplase 50 and 100 mg vial, plus 50 or 100 mL sterile water for injection for reconstitution.

Reconstituted vials are stable up to 24 hours at room temperature and in fridge.

Incompatible with bacteriostatic water for injection as preservatives can interact with alteplase.

Limited stability information available, concentrations of 0.1 and 0.05 mg/mL in NS have been used successfully and stability for 24 hours at room temperature is assumed.

For drug-drug compatibility contact Pharmacy.

Superficial or surface bleeding at puncture sites. Apply local pressure.

Serious internal bleeding, e.g. retroperitoneal, intracerebral: Discontinue infusion and, if necessary, administer cryoprecipitate and packed red blood cells. Tranexamic acid may be considered in an emergency. Do not use dextran.

Anaphylactoid reaction, laryngeal edema, rash, urticaria (rare).

Reperfusion arrhythmias, hypotension; when used for acute MI.

Cerebral edema, cerebral herniation, seizure, new ischemic stroke; when used for ischemic stroke.

Ischemic stroke: 0.9 mg/kg (max 90 mg) over 60 minutes, with 10% of total dose as a bolus at the start of the infusion.

Pulmonary embolism: 100 mg over 2 hours.

Acute MI: Initial dose 15 mg, then 0.75 mg/kg body weight over 30 minutes, not to exceed 50 mg, then 0.5 mg/kg over 60 minutes, not to exceed 35 mg. In SHR alteplase has been replaced with tenecteplase for this indication.

There is no generally accepted dosing regimen, preferred method of infusion or consensus regarding the use of concomitant anticoagulation.

Continuous infusion: starting dose of 0.25 - 1 mg/hour is recommended. Suggest 2 mg/hour x 4 hours then 0.5 mg/hour. Doses of up to 10 mg/hour and 0.1 mg/kg/hour have been studied and are associated with an increased risk of bleeding.

Intra-thrombus bolus or lacing: may decrease the duration of treatment and may be of advantage in acutely ischemic limbs. Must be weighed against the possible increased risk of hemorrhage.

One study used 5 mg boluses at 10 minute intervals to a maximum of 15 mg followed by an infusion as above.

No specific changes are necessary.

Limited information available at this time.

No information available at this time.

Correction of catheter occlusion: alteplase 2mg (Cathflo®) is indicated for correction of catheter occlusion.

Intra-pleural use: Adults - instill 10 mg (5 x 2 mg vials) into chest tube. Pediatrics (age greater than 2 years) – instill 2 mg into chest tube. Contact Pharmacy for further instructions (see SHR Pharmacy Department Clinical Policy and Procedure manual 25:30.08 re: Alteplase (tPA) for Intrapleural Use).

Manufacturers have an extensive return policy. Please return any unused alteplase to the pharmacy for credit.
ALTEPLASE intravenous- REFERENCES


11. Personal communication. Dr I. H. Weir. Section Head; Angiography and Interventional Radiology, Department of Medical Imaging. VIHA (South Island) Nov 8, 2002.

12. SHR Approved Clinical Health Record Form # 101779 (06/02) – “Activase® - rt – PA (Alteplase) for Acute Ischemic Stroke Patients”.


   - t-PA can be started within 3 - 4.5 hours of symptom onset
     - recommended within 3 hours (ACCP Grade 1A, AHA/ASA Class I, Level A)
     - suggested if 3 - 4.5 hours after symptom onset (ACCP Grade 2C, AHA/ASA Class I, Level B)

17. SHR Acute Stroke Thrombolytic (tPA) Administration Order Set 2014

   Dec. 2014 – made a few changes re: contraindications on p. 1 (including referral to Appendix A of SHR Acute Care Stroke PPOs for inclusion/exclusion criteria) and added in ability of Critical Care Personnel and assigned/certified Stroke or Neuroscience RN (RUH) (this is the wording requested by Ruth Whelan and Ann Saulnier 6300) to administer and monitor alteplase infusions (after bolus dose administered by physician).