Alteplase Intravenous for Adults

Who can administer

Alteplase for SYSTEMIC use: Doctor only

[PR]Cathflo [(unlicensed)]: May be administered by registered competent doctor or nurse/midwife

Cathflo Activase [(unlicensed)]: May be administered by registered competent doctor or nurse/midwife

Important information

- This monograph covers the use of alteplase in **acute stroke, acute PE with haemodynamic instability and acute MI**
- For use in **Catheter-directed Thrombolysis**- see separate monograph
- For use in **PE (low dose for intermediate/high risk)- unlicensed-**see separate monograph
- With the exception of MI or stroke"protocols", or central venous catheter clearance,the decision to thrombolyse should be made by a **consultant**
- In **myocardial infarction,** the regimen will depend on time between onset of symptoms and treatment time

Available preparations

Use	Preparation to use
Unblocking central venous catheters	[PR]Cathflo or Cathflo Activase [(unlicensed)]**2mg vial (overage contained in vial- see reconstitution details)**
All other uses	Actilyse **10mg** vial (with 10ml Water for Injection provided) Actilyse **20mg** vial (with 20ml Water for Injection provided) Actilyse **50mg** vial (with 50ml Water for Injection provided)

Reconstitution

Final concentration required	2mg vial	10mg vial	20mg vial	50mg vial
1mg per ml	Add 2.2mL Water for Injection, to produce a 1mg/ml solution. May be further diluted with Sodium Chloride 0.9% up to a maximum volume of 10ml, if lumen volume is more than 2ml	Add 10ml of solution provided	Add 20ml of solution provided	Add 50ml of solution provided
2mg per ml		Add 5ml of solution provided	Add 10ml of solution provided	Add 25ml of solution provided

- For the 10mg vial size, a syringe may be used to transfer the required volume of diluent to the vial
- For the 20mg and 50mg vial, a transfer needle is provided
- **AVOID VIGOROUS SHAKING OF THE PRODUCT- as foaming may occur**

Infusion fluids

- Can be used without further dilution once reconstituted as above
- If required, it can be diluted further with Sodium chloride 0.9% to a concentration NOT less than 0.2mg/ml (i.e. at least 20**mg** drug in 100ml)

Methods of intravenous administration

The choice of route (bolus injection vs infusion depends on the indication - see under 'dose' below)

Bolus intravenous injection [ref 1]

- Administer required dose over 1 to 2 minutes (Pulmonary embolism)
- Administer required dose over 3 to 5 minutes (Myocardial infarction)

Intermittent intravenous infusion (administer using an electronically controlled infusion device)

- No need for further dilution
- Administer required dose over time specified under 'dose' below
- The residual volume in the infusion line must be flushed through at the same rate to avoid significant underdosing

Dose in adults

- Assuming all contraindications etc have been checked the following doses may be used.
- Carefully select the correct indication below

1: Thrombolytic treatment in acute myocardial infarction: 90 minutes (accelerated) dose regimen

(for patients in whom treatment can be started **within 6 hours** of symptom onset)

Weight = 65kg or more	**Weight less than 65kg**
15mg iv bolus, followed by (see below)	15mg iv bolus, followed by (see below)
50mg infused over 30 minutes, followed by (see below)	0.75mg/kg (max 50mg) infusion over 30 minutes, followed by (see below)
35mg over 60 minutes (max total dose =100mg)	0.5mg/kg (maximum 35mg) over 60 minutes

2: Thrombolytic treatment in acute myocardial infarction: Three hour dose regimen (for patients in whom treatment can be started **between six and twelve hours** after symptom onset)

- Give 10mg as intravenous bolus injection
- Then give 50mg as an infusion over the first hour (CAUTION: if less than 40kg see last point below)
- Followed by infusions of 10mg over 30 minutes until the maximal **total** dose of 100mg or ~1.5mg/kg (**whichever is less**), over 3 hours is achieved
- Total dose for patients weighing less than 65kg cannot exceed 1.5mg/kg

3: Thrombolytic treatment in acute massive pulmonary embolism with haemodynamic instability (specialist use only)

- A total of 100mg should be given in two hours, as follows:
- Give 10mg as a bolus intravenous injection
- Follow with an infusion of 90mg over two hours

- **Maximum total dose of 1.5mg/kg** for patients weighing less than 65kg
- After treatment with alteplase, **heparin therapy** should be initiated (or resumed) when aPTT values are less than twice the upper limit of normal - see green Heparin prescription sheet

4: Fibrinolytic treatment of Acute ischaemic stroke

Treatment MUST be performed by a **physician specialised in NEUROLOGICAL** care

- Treatment must be started within 4.5 hours of onset of the stroke symptoms and after prior exclusion of intracranial haemorrhage by means of appropriate imaging techniques
- The recommended dose is 0.9mg per kg **(maximum 90mg)**
- The first 10% of this dose should be administered as an intravenous bolus dose
- The remainder of the dose should be infused over 60 minutes

5: Catheter-directed thrombolysis by an interventional radiologist (must be consultant authorised)- see separate monograph

6. Central venous catheter clearance

Method (Use [PR]Cathflo or Cathflo Activase [(unlicensed)]preparation)

- Instil the appropriate dose into the blocked catheter **after prescribing the treatment on the drug chart**
- For catheters with an internal volume of 2ml or less - use the reconstituted [PR]Cathflo or Cathflo Activase [(unlicensed)] (2mg in 2ml)
- For catheters with an internal volume of greater than 2ml- dilute up the product further with Sodium chloride 0.9%- eg if the catheter volume is 2.7ml, dilute up theÂ [PR]Cathflo or Cathflo Activase [(unlicensed)] to 2mg in 2.7ml (maximum allowable dilution is 2mg in 10ml)
- After 30 minutes of dwell time, assess catheter function by attempting to aspirate blood
- If the catheter is still not functional, leave the [PR]Cathflo or Cathflo Activase [(unlicensed)] in the catheter for a further 90 minutes (total dwell time 120 minutes), and then try and aspirate blood
- If catheter function is still not restored, a second dose (same amount as first dose), can be instilled. Again, leave this 30 minutes before trying to aspirate blood, and if still not working, then another 90 minutes, as before)
- If it is still not functional, consider device replacement
- If catheter function has been restored (at any point during the above sequence), aspirate 4 to 5ml blood, to remove [PR]Cathflo or Cathflo Activase [(unlicensed)] and residual clot, and gently irrigate the catheter with Sodium Chloride 0.9%
- Maximum dose 4mg (2 x 2mg) for any one occasion

Storage

Actilyse 10mg, 20mg, 50mg vials: Store below 25^{0}C

Actilyse Cathflo 2mg vials: Store between 2 and 8^{0}C

References

Actilyse 10mg, 20mg, 50mg vials: SPC March 2022

Cathflo Activase [(unlicensed)] 2mg vials: Online information downloaded 25/01/2023

[PR]Cathflo SPC - received October 25th 2023

1. Injectable Medicines Guide Medusa, downloaded 20/01/2023

Therapeutic classification

Fibrinolytic agent

BNF

Myocardial ischaemia