Alteplase: Low dose for Intermediate/High risk PE

Who can administer

Administration restricted- see Appendix 1 below

Important information

- **Important: Separate protocol for HI-PEITHO patient - available from Clinical trials**
- **Unlicensed indication**
- **Patients MUST be discussed with some or all of the following:**
  - Consultant Anaesthetist/Intensivist
  - Consultant Respiratory physician
  - Consultant Haematologist with special interest in coagulation
  - Consultant Radiologist
  - Consultant Cardiologist
- Consider in patient with acute PE where there is clinical concern **AND**
  - Evidence of **right heart strain** (increased troponin+/- increased pro-BNP) and/or RV dilatation on echo
  - Patients **not improving** on anticoagulation or **worsening of biomarkers**/RV strain despite anticoagulation
  - Patient **not a candidate** for full dose (100mg) alteplase due to concerns regarding bleeding or who **do not meet criteria** for 100mg dose for acute massive pulmonary embolism with haemodynamic instability

  For use in thrombolysis **(acute MI)**, **acute massive PE**, **acute ischaemic stroke** - see separate monograph

- For use in **Catheter-directed Thrombolysis**- see separate monograph

Available preparations

- Actilyse **10mg**Â vial (with 10ml Water for Injection provided)

Reconstitution

- Use 10ml Water for Injection provided

Infusion fluids

Sodium chloride 0.9%Â **only**

Dilution	Concentration produced
10mg added to 40ml infusion fluid to produce a final volume of 50ml	1mg per 5ml

The product must only be diluted and reconstituted as outlined here, due to stability issues at other concentrationsÂ (SPC)

Methods of intravenous administration

Bolus intravenous injectionÂ [ref 1]

- Administer required dose over 1 to 2 minutesÂ

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

- Administer required dose as per Dose below
- May be administered via a peripheral cannula in the Critical care setting
- **Syringe must be changed after 8 hours (no stability data beyondÂ 8 hours at room temperature)**

Dose in adults

Pulmonary embolism (Low dose for Intermediate/High risk PE)(for patients meeting criteria in Important information above)

- Administer 10mg as a bolus intravenous injection
- Follow bolus injection with an infusion of 1mg/hour (**5ml**/hour) for 24 hours or until clinical improvement
- Concomitant heparin administration is required (either UFH or LMWH depending on patient's clinical condition)

For doses in other indications see separate monographs

- For use in thrombolysis **(acute MI)**, **acute massive PE**, **acute ischaemic stroke** - see separate monograph
- For use in **Catheter-directed Thrombolysis**- see separate monograph

Monitoring

- Baseline: Check PT, aPTT, FBC, **Clauss**Â fibrinogen, troponin, pro-BNP
- Recheck Coag including Clauss fibrinogen 8 hourly (dependingÂ on heparin regimen)Â **or**Â if bleeding
- Risk of bleeding is lower with this regimen than the full dose alteplase regimen
- Ensure Clauss fibrinogen is greater than 1.0g/L

Storage

- Store below 25^{0}C
- ***Syringe must be changed after 8 hours (no stability data beyondÂ 8 hours at room temperature)***

References

1: Injectable Medicines Administration guide (downloaded from Medusa 17/07/2025)

Locally produced guidelines:Â approved by Dr Gerry O Sullivan (IR), Dr. Ruth Gilmore (Haematologist).16/07/2025

Therapeutic classification

- Fibrinolytic agent