

## 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** vial (with 10ml Water for Injection provided)

## Reconstitution

- Use 10ml Water for Injection provided

## Infusion fluids

Sodium chloride 0.9% **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 concentrations (SPC)**

# Methods of intravenous administration

## **Bolus intravenous injection<sup>1</sup>**

- Administer required dose over 1 to 2 minutes

## **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 beyond 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** fibrinogen, troponin, pro-BNP
- Recheck Coag including Clauss fibrinogen 8 hourly (depending on heparin regimen) **or** 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°C
- **Syringe must be changed after 8 hours (no stability data beyond 8 hours at room temperature)**

## References

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

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

## Therapeutic classification

- Fibrinolytic agent