University HOSPITAL
Newark, NJ

Tenecteplase Medication Guide

Indications/Dosing:

Indication	Tenecteplase Dose
Acute Ischemic Stroke (AIS) within 4.5 hours of last known well – *off label*	0.25 mg/kg, maximum 25 mg
Massive pulmonary embolism – *off label*	30 mg for <60 kg 35 mg for 60-69 kg 40 mg for 70-79 kg 45 mg for 80-89 kg 50 mg for ≥ 90 kg
Cardiac arrest secondary to pulmonary embolism – *off label*	
STEMI	

Mechanism of Action/Kinetics:

Tenecteplase binds to fibrin and converts plasminogen to plasmin. Tenecteplase is essentially alteplase with the exception of 3 point mutations and is more fibrin specific, more resistant to plasminogen activator inhibitor -1 (PAI-1), with a longer duration of action compared to alteplase

Comparison of Thrombolytic Agents

Thrombolytic	Infusion time	Generation	Direct plasminogen activator?	Half-life, min	Fibrin selectivity	PAI resistance*	FDA Indication	Formulary?
Alteplase	120 min (PE), 60 min (stroke), 1 min (cardiac arrest)	Second	Yes	4-8	++	++	PE, AIS, STEMI	Yes
Tenecteplase	5-10 seconds	Third	Yes	20-24 (initial), 90-130 (terminal)	+++	+++	STEMI	Yes

**PAI is a 52-kDa circulating glycoprotein that is the primary native of plasminogen-activating enzymes, and greater PAI resistance confers a longer duration of fibrinolysis*

Preparation & Administration (see page 3)

- Remove the tenecteplase 50mg/10mL kit after the order is placed in Epic
- Remove shield assembly from supplied 10 mL syringe
- Withdraw 10 mL of Sterile Water for Injection (SWFI) from the supplied diluent vial. Note: Do not use Bacteriostatic Water for Injection
- Inject 10 mL of SWFI into the tenecteplase vial directing the diluent stream into the powder, slight foaming is common
- Gently swirl until contents are completely dissolved (usually ~ 1 minute), DO NOT SHAKE
    - **Reconstituted preparation contains tenecteplase 5 mg/mL**
- Inspect the solution for particulate matter or discoloration (should be a colorless to pale yellow solution)
- Withdraw the appropriate volume of solution
- Administer as an IV bolus over 5 to 10 seconds using a peripheral vein
- Flush a dextrose-containing line with a saline-containing solution prior to and following administration (precipitation may occur when tenecteplase is administered in an IV line containing dextrose).

Contraindications:

- Overall, tenecteplase has similar contraindications to other thrombolytics, and should be used with caution in patients who are at high risk of bleeding. See *Stroke Toolkit* on *UH Clinical Links* site for more detailed list of contraindications.

Monitoring:

- For stroke patients, please utilize the green sheet, located in the Emergency Department, as a monitoring aid
    - A neuro assessment and vital signs (BP, HR, RR, SpO2) should be documented for 24 hours from the time thrombolysis is given: every 15 minutes for 2 hours (8 times), every 30 minutes for 6 hour (12 times), every 60 minutes for 16 hours (16 times), for a total of 24 hours.

Reversal Recommendations:

- *See UH Anticoagulation Reversal Guidelines for recommendations*

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Ischemic Stroke Thrombolysis

Patient deemed thrombolysis candidate by Neurology BAT Team

Contraindication to fibrinolysis?
(See *Stroke Toolkit* on clinical links for more detailed list of contraindications)

this list of contraindications is a guideline and a physician experienced in the treatment of acute stroke may modify the list on a case by case basis

Exclusion Criteria

- Current or history of intracranial hemorrhage
- Ischemic stroke within 3 months
- Symptoms suggestive of SAH
- Arterial puncture in non-compressible site within 7 days
- Intracranial or spinal surgery within 3 months
- Recent significant head trauma within 3 months
- Known structural intracranial cerebrovascular disease
- Known malignant intracranial neoplasm
- Blood pressure SBP > 185 mmHg or DBP > 110 mmHg
- Active internal bleeding
- Bleeding diathesis: platelets <100,000 mm3, aPTT> 40s, PT > 15 s, INR >1.7
- Anticoagulation contraindications (last dose within):
  - Apixiban (Eliquis®) within 48 hours**
  - Dabigatran (Pradaxa®) within 72 hours**
  - Enoxaparin (Lovenox®) therapeutic dose within 24 hours**
  - Heparin therapeutic dose and aPTT > ULN**
  - Rivaroxaban (Xarelto®) within 48 hours**
  - Warfarin (Coumadin®) and INR> 1.7

  *** for patients with normal renal function, activity may be prolonged in patients with renal impairment*
- Blood glucose <50 mg/dL or > 400 mg/dL
- CT shows frank hypo-density or extensive hypo-attenuation
- Symptoms consistent with infective endocarditis
- Known or suspected aortic arch dissection
- Gastrointestinal hemorrhage within previous 21 days
- Gastrointestinal malignancy

Additional Exclusion Criteria for Onset 3-4.5 Hours

- Imaging evidence of ischemic injury involving more than 1/3 middle cerebral artery territory

Relative Exclusion Criteria

- Major surgery/serious trauma within previous 14 days
- Lumbar or arterial puncture in previous 7 days
- Recent or active menorrhagia
- Pregnancy or post-partum (<14 days)
- Hemorrhagic ophthalmic condition
- Acute myocardial infarction within 3 months
- Other cardiac condition: acute pericarditis, known LV thrombus, cardiac myxoma, papillary fibroelastoma
- Intracranial arterial dissection
- Large burden of cerebral micro-bleed on MRI
- Current systemic malignancy

Consider risk vs. benefit:

- Only minor, non-disabling symptoms; or rapidly improving stroke symptoms (clearing spontaneously)
- Seizure at onset of symptoms, only if residual symptoms are thought to be post-ictal etiology

Relative Exclusion Criteria for Onset 3-4.5 hours

- NIHSS score ≥ 25

Consider risk vs. benefit:

- Oral anticoagulant use
- History of prior stroke AND diabetes mellitus

No Contraindication to fibrinolysis

Contraindication to fibrinolysis

Refer to Stroke Team or Emergency Medicine team for alternative therapy

Wake-up stroke

MRI

Refer to Neurology for thrombolytic recommendation

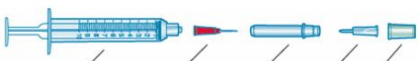
Although rare, in the setting of wake-up stoke, ***alteplase*** *[0.9 mg/kg (max 90 mg), 10% bolus (max 9 mg) over 1 min, remaining infusion (max 81 mg) over 60 min] can be considered*

Bolus to be administered by Neurology MD

Last known well within 4.5 hours

Time out by neuro MD to review patient criteria, inclusion/exclusion criteria, and dosing

Tenecteplase (TNK): 0.25 mg/kg (max 25 mg/5ml)
Administration: single IV push over 5-10 seconds given by Neurology MD, refer to page 3 for preparation instructions



Endovascular intervention if applicable

This tip sheet is intended to be flexible. They serve as reference points or recommendations, not rigid criteria. Guidelines should be followed in most cases, but there is an understanding that, depending on the patient, setting, circumstances or factors, guidelines can and should be tailored to fit individual needs.

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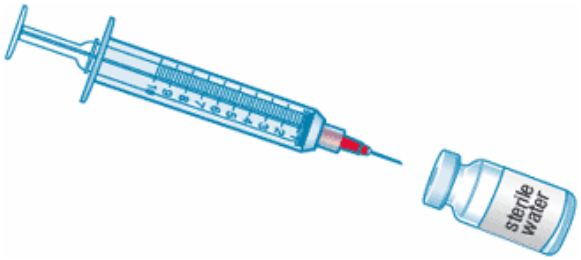
Preparation for Tenecteplase Administration

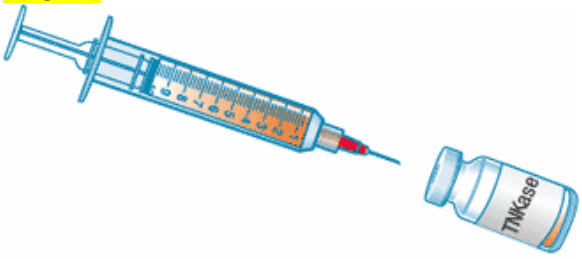
Full instructions on reconstitution and administration
Full video on dosing and administration

Step 1: Remove the shield assembly from the supplied B-D 10 mL syringe with TwinPak™ Dual Cannula Device.

Step 2: Aseptically WITHDRAW 10 mL of Sterile Water for Injection, USP, using the B-D 10 mL syringe with TwinPak™ Dual Cannula Device included in the kit. Do not use Bacteriostatic Water for Injection, USP.

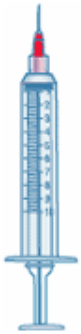


Step 3: INJECT entire contents (10 mL) into the TNKase vial, directing the diluent into the powder. Slight foaming upon reconstitution is not unusual; any large bubbles will dissipate if the product is allowed to stand undisturbed for several minutes. **Final concentration is 50 mg/10 mL (5mg/mL)**

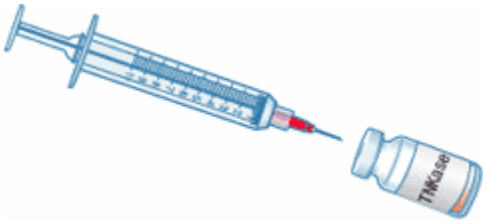


Step 4: GENTLY SWIRL until contents are completely dissolved. DO NOT SHAKE. Solution should be colorless or pale yellow and transparent. Once the appropriate dose of TNKase is drawn into the syringe, stand the shield vertically and recap the red tab cannula.

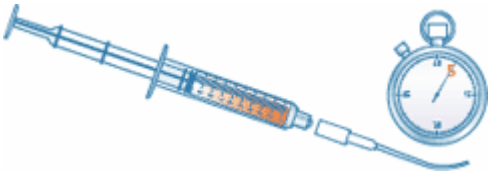
Step 5: Determine the correct dose of TNKase based on patient weight. TNKase is for IV administration only.



Step 6: WITHDRAW the appropriate volume of solution based on patient weight. **The recommended total dose should not exceed 25 mg for stroke, 50 mg for all other indications.** Discard solution remaining in the vial.



Step 7: FLUSH a dextrose-containing line with a saline-containing solution prior to and following administration (precipitation may occur when TNKase is administered in an IV line containing dextrose). **ADMINISTER as an IV BOLUS over 5 seconds.**



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