FOR ADULT PATIENTS WITH ACUTE ISCHEMIC STROKE (AIS)[1]

Dosing information[1]

TNKase® is administered as a single 5-second IV bolus

New packaging coming soon.
Now approved in 25-mg and 50-mg vials.

The maximum recommended dose is 25 mg (5 mL)

Initiate treatment as soon as possible within 3 hours of symptom onset

Recommended dosage for AIS:

Patient weight (kg)	TNKase (mg)	Volume TNKase to be administered (mL)
<60 kg	15 mg	3 mL
≥60 to <70 kg	17.5 mg	3.5 mL
≥70 to <80 kg	20 mg	4 mL
≥80 to <90 kg	22.5 mg	4.5 mL
≥90 kg	25 mg	5 mL

Individualize dosing based on patient's weight per table above.

- During and following TNKase administration for the treatment of AIS, frequently monitor and control blood pressure
- In patients without recent use of oral anticoagulants or heparin, TNKase treatment can be initiated prior to the availability of coagulation study results. If the pretreatment international normalization ratio is greater than 1.7 or the activated partial thromboplastin time is elevated, closely monitor patients

Indication

Acute Ischemic Stroke

TNKase (tenecteplase) is indicated for the treatment of acute ischemic stroke (AIS) in adults.

Important Safety Information

Contraindications

TNKase is contraindicated in any patients with:

- Active internal bleeding
- Intracranial or intraspinal surgery or trauma within 2 months
- Known bleeding diathesis
- Current severe uncontrolled hypertension
- Presence of intracranial conditions that may increase the risk of bleeding (eg, intracranial neoplasm, arteriovenous malformation, or aneurysm)

TNKase is also contraindicated in patients for the treatment of AIS with:

- Active intracranial hemorrhage

Please see additional Important Safety Information throughout and full Prescribing Information.

Scan me

to view the TNKase dosing and administration video

SINGLE-BOLUS
TNKase®
Tenecteplase

Select Preparation and Administration of TNKase[1,2]

If using the 25-mg TNKase vial:

Step 1

Using a sterile syringe, aseptically **withdraw the Sterile Water for Injection** from the diluent vial. Only use the supplied Sterile Water for Injection diluent vial.

NOTE: If using the 50-mg TNKase vial, withdraw 10 mL of Sterile Water for Injection.

Step 2

RECONSTITUTE the 25-mg TNKase vial aseptically with 5.2 mL of Sterile Water for Injection by directing the stream into the lyophilized powder to obtain a final concentration of 5 mg/mL. Slight foaming upon reconstitution is not unusual; any large bubbles will dissipate if the product is allowed to stand undisturbed for several minutes.

NOTE: If using the 50-mg TNKase vial, aseptically reconstitute the 10-mL Sterile Water for Injection to obtain a final concentration of 5 mg/mL.

Step 3

GENTLY SWIRL until contents are completely dissolved. DO NOT SHAKE.
The reconstituted solution should be colorless or pale yellow and transparent. Because TNKase contains no antibacterial preservatives, reconstitute immediately before use. If the reconstituted TNKase is not used immediately, refrigerate the TNKase vial at 2°C to 8°C (36°F to 46°F) and use within 8 hours.

Step 4

DETERMINE the appropriate dose of TNKase (see table on previous page). WITHDRAW the required volume (in milliliters) from the reconstituted vial into a syringe. Discard any unused solution. **VISUALLY INSPECT** the reconstituted product in the syringe for particulate matter and discoloration prior to administration.

Step 5

Precipitation may occur when TNKase is administered in an intravenous line containing dextrose. **FLUSH** dextrose-containing lines with 0.9% Sodium Chloride Injection solution prior to and following single bolus administration of TNKase.

Step 6

ADMINISTER reconstituted TNKase as a single IV bolus over 5 seconds.

Step 7

ASSESS AND MONITOR patients according to each institution's protocol. Check for bleeding and signs of hypersensitivity. Monitor blood pressure. Perform neurological assessments. Consult the American Heart Association and American Stroke Association Guidelines for acute ischemic stroke for more information.

Important Safety Information (cont'd)

Warnings and Precautions

Bleeding

TNKase can cause significant, sometimes fatal, internal or external bleeding, especially at arterial and venous puncture sites. Concomitant use of other drugs that impair hemostasis increases the risk of bleeding. Avoid intramuscular injections and trauma to the patient while on TNKase. Perform arterial and venous punctures carefully and only as required. To minimize bleeding from noncompressible sites, avoid internal jugular and subclavian venous punctures. If an arterial puncture is necessary during TNKase administration, use an upper extremity vessel that is accessible to manual compression, apply pressure for at least 30 minutes, and monitor the puncture site closely. Should serious bleeding that is not controlled by local pressure occur, discontinue any concomitant heparin or antiplatelet agents immediately and treat appropriately.

Please see additional Important Safety Information throughout and full Prescribing Information.

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Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Bleeding (cont'd)

The concomitant administration of heparin and aspirin with and following administration of TNKase for the treatment of acute ischemic stroke during the first 24 hours after symptom onset has not been investigated. Because heparin, aspirin, or TNKase may cause bleeding complications, carefully monitor for bleeding, especially at arterial puncture sites. Hemorrhage can occur 1 or more days after administration of TNKase, while patients are still receiving anticoagulant therapy.

In the following conditions, the risks of bleeding with TNKase therapy for all approved indications are increased and should be weighed against the anticipated benefits: recent major surgery or procedure, (eg, coronary artery bypass graft, obstetrical delivery, organ biopsy, previous puncture of noncompressible vessels); cerebrovascular disease; recent intracranial hemorrhage (if not contraindicated); recent gastrointestinal or genitourinary bleeding; recent trauma; hypertension: systolic BP above 175 mm Hg or diastolic BP above 110 mm Hg; acute pericarditis; subacute bacterial endocarditis; hemostatic defects including those secondary to severe hepatic or renal disease; significant hepatic dysfunction; pregnancy; diabetic hemorrhagic retinopathy or other hemorrhagic ophthalmic conditions; septic thrombophlebitis or occluded AV cannula at seriously infected site; advanced age; patients currently receiving anticoagulants; or any other condition in which bleeding constitutes a significant hazard or would be particularly difficult to manage because of its location.

Hypersensitivity

Hypersensitivity, including urticarial/anaphylactic reactions, have been reported after administration of TNKase (eg, anaphylaxis, angioedema, laryngeal edema, rash, and urticaria). Monitor patients treated with TNKase during and for several hours after administration. If symptoms of hypersensitivity occur, initiate appropriate therapy (eg, antihistamines, corticosteroids, or epinephrine).

Thromboembolism

The use of thrombolytics can increase the risk of thrombo-embolic events in patients with high likelihood of left heart thrombus, such as patients with mitral stenosis or atrial fibrillation.

Cholesterol Embolization

Cholesterol embolism has been reported in patients treated with thrombolytic agents. Investigate cause of any new embolic event and treat appropriately.

Arrhythmias

Coronary thrombolysis may result in arrhythmias associated with reperfusion. It is recommended that anti-arrhythmic therapy for bradycardia and/or ventricular irritability be available when TNKase is administered.

Adverse Reactions

The most common adverse reaction is bleeding.

Please see additional Important Safety Information throughout and full Prescribing Information.

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Important Safety Information (cont'd)

Drug Interactions

Drug/Laboratory Test Interactions

During TNKase therapy, results of coagulation tests and/or measures of fibrinolytic activity may be unreliable unless specific precautions are taken to prevent *in vitro* artifacts. Tenecteplase is an enzyme that, when present in blood in pharmacologic concentrations, remains active under *in vitro* conditions. This can lead to degradation of fibrinogen in blood samples removed for analysis.

Patient Counseling Information

Bleeding

Inform patients that bleeding can occur 1 or more days after administration of TNKase. Instruct patients to contact a healthcare provider if they experience signs or symptoms consistent with bleeding (eg, unusual bruising; pink or brown urine; red, black, or tarry stools; coughing up blood; vomiting blood or blood that looks like coffee grounds) or symptoms of a stroke.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

Please see full Prescribing Information for additional Important Safety Information.

References: 1. TNKase Prescribing Information. South San Francisco, CA. Genentech, Inc. **2.** Powers WJ, Rabinstein AA, Ackerson T, et al. Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2019;50(12):e344-e418. doi:10.1161/STR.0000000000000211

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