In the treatment of STEMI, consider

TNKase® (tenecteplase) SINGLE-BOLUS

DOSING INFORMATION

TNKase® (tenecteplase) is for intravenous administration only. The recommended total dose should not exceed 50 mg and is based upon patient weight.

Initiate treatment as soon as possible after the onset of STEMI symptoms.

Patient Weight (kg)	Patient Weight (lb)	TNKase (mg)	Reconstituted (5 mg/mL) TNKase (mL)
<60	<132	30	6
≥60 to <70	≥132 to <154	35	7
≥70 to <80	≥154 to <176	40	8
≥80 to <90	≥176 to <198	45	9
≥90	≥198	50	10

INDICATION

TNKase® (tenecteplase) is indicated to reduce the risk of death associated with acute ST elevation myocardial infarction (STEMI).

IMPORTANT SAFETY INFORMATION

Contraindications

TNKase is contraindicated in patients with: active internal bleeding; history of cerebrovascular accident; intracranial or intraspinal surgery or trauma within 2 months; intracranial neoplasm, arteriovenous malformation, or aneurysm; known bleeding diathesis; and severe uncontrolled hypertension.

Please see full Prescribing Information and additional Important Safety Information on the next page.

Genentech
A Member of the Roche Group

TNKase® (tenecteplase) SINGLE-BOLUS™

www.tnkase.com

SELECT RECONSTITUTION AND ADMINISTRATION

See Prescribing Information for complete directions.
(Use aseptic technique throughout.)

1. **WITHDRAW** 10 mL of Sterile Water for Injection, USP, from the supplied diluent vial using the red hub cannula syringe filling device. Only use the supplied Sterile Water for Injection, USP for reconstitution. See TNKase Package Insert for instructions on use of the dual cannula device.

2. **RECONSTITUTE** the vial with 10 mL Sterile Water for Injection, USP 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.

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

4. **WITHDRAW** the appropriate volume of solution based on patient weight. (See Dosing Information.) **The recommended total dose should not exceed 50 mg.** Discard solution remaining in the vial.

5. TNKase is incompatible with dextrose containing solutions. When used together, precipitation may occur. Flush dextrose containing lines with saline-containing solution before using TNKase. Stand the shield vertically on a flat surface (with green side down) and passively recap the red hub cannula.

6. **ADMINISTER** as an IV BOLUS over 5 seconds.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Bleeding

TNKase can cause bleeding, including intracranial hemorrhage and fatal bleeding. Concomitant use of other drugs that impair hemostasis increases the risk of bleeding.

Should serious bleeding that is not controlled by local pressure occur, discontinue any concomitant heparin or antiplatelet agents immediately and treat appropriately.

Avoid intramuscular injections and nonessential handling of the patient for the first few hours following treatment with 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 infusion, use an upper extremity vessel that is accessible to manual compression. Apply pressure for at least 30 minutes.

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.

Increased Risk of Heart Failure and Recurrent Ischemia when used with Planned Percutaneous Coronary Intervention (PCI) in STEMI

In a trial of patients with STEMI there were trends toward worse outcomes in the individual components of the primary endpoint between TNKase plus PCI versus PCI alone (mortality 6.7% vs. 4.9%, respectively; cardiogenic shock 6.3% vs. 4.8%, respectively; and CHF 12% vs. 9.2%, respectively). In addition, there were trends towards worse outcomes in recurrent MI (6.1% vs. 3.7%, respectively; $p = 0.03$) and repeat target vessel revascularization (6.6% vs. 3.4%, respectively; $p = 0.0045$) in patients receiving TNKase plus PCI versus PCI alone. In patients with large ST-segment elevation myocardial infarction, physicians should choose either thrombolysis or PCI as the primary treatment strategy for reperfusion. Rescue PCI or subsequent elective PCI may be performed after administration of thrombolytic therapies if medically appropriate; however, the optimal use of adjunctive antithrombotic and antiplatelet therapies in this setting is unknown.

Hypersensitivity

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

Adverse Reactions

The most frequent adverse reactions associated with TNKase are bleeding and hypersensitivity.

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.

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 and additional Important Safety Information.

TNKase® tenecteplase