

## PRODUCT MONOGRAPH

**PrTNKase<sup>®</sup>**

Tenecteplase

Powder for Solution - 50 mg/Vial  
Sterile, Lyophilized

Fibrinolytic Agent

Distributed by:  
Hoffmann-La Roche Limited  
2455 Meadowpine Boulevard  
Mississauga, Ontario  
L5N 6L7

Date of Approval:  
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Manufactured by:  
Genentech, Inc.  
California, U.S.A.

Submission Control No: 120211

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<sup>Pr</sup>TNKase®  
Tenecteplase

**This leaflet is part III of a three-part "Product Monograph" published when TNKase was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TNKase. Contact your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION****What the medication is used for:**

TNKase (tenecteplase) is used in adults to treat acute myocardial infarctions (heart attacks). Treatment should begin as soon as possible after symptoms start.

**What it does:**

TNKase belongs to a group of medicines called thrombolytics. This medicine dissolves blood clots that have formed in the blood vessels of the heart. This helps to prevent the damage caused by heart attacks and has been shown to save lives.

**When it should not be used:**

- if you are allergic to TNKase or any of the ingredients it contains

In addition, TNKase will not be given by your doctor if you have, or have recently had, an illness that increases your risk of bleeding, including:

- a bleeding disorder or recent history of bleeding
- stroke
- recent major surgery or trauma to your brain or spine
- brain tumour
- abnormality of the blood vessels or aneurysm
- severe high blood pressure

**What the medicinal ingredient is:**

Tenecteplase

**What the nonmedicinal ingredients are:**

L-arginine, phosphoric acid, polysorbate 20

**What dosage forms it comes in:**

A vial containing 50 mg (10,000 units) TNKase to be prepared for intravenous injection

**WARNINGS AND PRECAUTIONS**

BEFORE TNKase is given, your doctor will review the possible risks based on your medical condition and history, including if you have/had:

- recent major surgery
- stroke
- recent bleeding in the gut or urinary system
- recent trauma
- high blood pressure
- problems with your heart or heartbeat
- bleeding disorder
- severe liver failure
- pregnancy
- serious infection or inflammation
- advanced age
- taken medications that affect blood clotting

**INTERACTIONS WITH THIS MEDICATION**

Medications that affect blood clotting may increase the risk of bleeding prior to, during or after therapy with TNKase.

**PROPER USE OF THIS MEDICATION**

TNKase is given as a single injection into a vein. Your doctor will give TNKase as soon as possible after your chest pain starts.

**Usual dose:**

The doctor calculates your dose of TNKase according to your body weight, with a maximum dose of 50 mg (10,000 units). Acetylsalicylic acid (ASA) and heparin are usually given as part of your treatment.

**Overdose:**

In the event of overdose, there may be an increased risk of bleeding. Any patients receiving greater than the recommended dose should be carefully monitored.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, TNKase can have side effects.

The most frequent side effect associated with TNKase is bleeding. Most of the time the bleeding is minor, however sometimes major bleeding can occur requiring blood transfusion or leading to circulation problems. If major bleeding occurs, your doctor will

stop any medications that can make bleeding worse. Death or permanent disability can occur in patients who experience stroke or other serious bleeding episodes.

Allergic-type reactions such as swelling of the skin and throat, rash or hives can occur.

Other serious side effects affecting the heart and lungs have been reported among patients receiving TNKase and are often caused by the underlying disease. These effects can be life-threatening and may lead to death.

*This is not a complete list of side effects. For any unexpected effects while taking TNKase, contact your doctor or pharmacist.*

## HOW TO STORE IT

Store the vials below 30°C or in a refrigerator at 2°C - 8°C.

The reconstituted solution may be stored for 8 hours in a refrigerator at 2°C - 8°C.

## **REPORTING SUSPECTED SIDE EFFECTS**

**To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:**

**By toll-free telephone; 866-234-2345**

**By toll-free fax: 866-678-6789**

**Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)**

**By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)**

**By regular mail:**

**Canada Vigilance National Office  
Marketed Health Products Safety and  
Effectiveness Information Bureau  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada  
Tunney's Pasture, AL 0701C  
Ottawa ON K1A 0K9**

***NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.***

## MORE INFORMATION

This brochure does not contain all known information about TNKase. If you have any further questions or concerns about your treatment with TNKase, please contact your doctor.

This document plus the full product monograph, prepared for health professionals can be found at: [www.rochecanada.com](http://www.rochecanada.com)

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Last revised: