PRODUCT MONOGRAPH

PrTNKase®

tenecteplase for injection

Powder for Solution - 50 mg/Vial
Sterile, Lyophilized

Fibrinolytic Agent

Distributed by:
Hoffmann-La Roche Limited
7070 Mississauga Road
Mississauga, Ontario
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PART III: CONSUMER INFORMATION

PrTNKase®
tenecteplase for injection

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 for injection) 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 is involved in the process to dissolve blood clots that have formed in the blood vessels of the heart. This helps to prevent the damage caused by heart attacks and when given at the right time it 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 non-medicinal 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 gastrointestinal or urinary systems
- 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 instability in blood pressure which may decrease blood flow to organs. 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

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at
www.healthcanada.gc.ca/medeffect
Call toll-free at 1-866-234-2345
Complete a Canada Vigilance Reporting Form and:
- Fax toll-free to 1-866-678-6789,
or
- Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.rochecanada.com or by contacting the sponsor Hoffmann-La Roche Limited, at: 1-888-762-4388.

This leaflet was prepared by Hoffmann-La Roche Limited

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