TNKPLASE®
(Tenecteplase)

TNKPLASE (Tenecteplase) is a tissue plasminogen activator (tPA) produced by recombinant DNA technology using an established mammalian cell line (Chinese Hamster Ovary cells). Tenecteplase is a 527 amino acid glycoprotein developed by introducing the following modifications to the complementary DNA (cDNA) for natural human tPA: a substitution of threonine 103 with asparagine, and a substitution of asparagine 117 with glutamine, both within the kringle 1 domain, and a tetra-alanine substitution at amino acids 296–299 in the protease domain.

Dosage Form and Strength

Tenecteplase Lyophilized powder for Injection, 30mg/ Vial

Tenecteplase Lyophilized powder for Injection, 40mg/ Vial

Tenecteplase Lyophilized powder for Injection, 50mg/ Vial

Clinical Pharmacology – Mechanism of Action

Tenecteplase is a modified form of human tissue plasminogen activator (tPA) that binds to fibrin and converts plasminogen to plasmin. In the presence of fibrin, in vitro studies demonstrate that Tenecteplase is a recombinant fibrin-specific plasminogen activator that is derived from native t-PA by modifications at three sites of the protein structure. Tenecteplase binds to fibrin-rich clots via the fibronectin finger-like domain and the Kringle 2 domain. The protease domain then cleaves the Arg/Val bond in plasminogen to form plasmin. Plasmin in turn degrades the fibrin matrix of the thrombus, thereby exerting its thrombolytic action.

Indication

Tenecteplase is indicated in adults for the thrombolytic treatment of suspected myocardial infarction with persistent ST elevation or recent left Bundle Branch Block within 6 hours after the onset of acute myocardial infarction (AMI) symptoms.

Dosage and Administration

Hetero-Tenecteplase was administered intravenously on the basis of body weight, with a maximum dose of 10,000 International units.

Storage and Handling

Do not store above 30°C. Keep the container in the outer carton in order to protect from light.

Packaging Information

Tenecteplase is a powder and solvent for solution for injection.
The reconstituted preparation of Tenecteplase is clear and colorless to a slightly yellow solution
Tenecteplase belongs to a group of medicines called thrombolytic agents. These medicines help to dissolve blood clots.
Tenecteplase is a recombinant fibrin-specific plasminogen activator.
Tenecteplase is used to treat myocardial infarctions (heart attacks) within 6 hours after the onset of symptoms and helps to dissolve the 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.

Reconstitution And Administration

50 mg Vial:

Each vial contains 10,000 units (50 mg) Tenecteplase. Each vial contains 10 ml solvent.
The reconstituted solution contains 1,000 units (5 mg) Tenecteplase per ml.

40 mg Vial:

Each vial contains 8000 units (40 mg) Tenecteplase. Each vial contains 10 ml solvent.
The reconstituted solution (Diluted with 8 ml) contains 1,000 units (5 mg) Tenecteplase per ml.

30 mg Vial:

Each vial contains 6000 units (30 mg) Tenecteplase. Each vial contains 10 ml solvent.
The reconstituted solution (Diluted with 6 ml) contains 1,000 units (5 mg) Tenecteplase per ml.

Manufactured By

M/s. Hetero Biopharma Limited,
Survey No. 458 (Part), TSIIC Formulation - SEZ,
Polepally Village, Jadcherla Mandal, Mahaboobnagar District – 509 301,
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