“Retelies®”

Generic name:

Reteplase

Category:

Thrombolytic

Pharmacodynamic:

Reteplase is the r-PA (recombinant plasminogen activator) that catalyzes the cleavage of endogenous plasminogen to generate plasmin. Plasmin in turn degrades the fibrin matrix of the thrombus.

Pharmacokinetics:

Reteplase is cleared primarily by liver and kidneys. The half- life is 13 to 16 minutes.

Indications:

Management of acute MI, to reduce incidence of CHF and mortality associated with an acute MI and other arteriovenous occlusions.

Off-label uses:

Thrombolytic treatment of acute and chronic deep venous thrombosis; treatment of massive pulmonary embolism; use in conjunction with heparin and percutaneous transluminal angioplasty; treatment of thrombosed polytetrafluoroethylene hemodialysis arteriovenous grafts.

Dosage and Administration:

▪Retelies® is for intravenous administration only.reteplase is FDA-approved for acute myocardial infarction (AMI) and is administered as two bolus injections of 18 mg. Each bolus is administered over 2 minutes. The second bolus is given 30 minutes after the first bolus injection. No other medication should be injected or infused in the same intravenous line. No other medication should be added to the injection solution containing Retelies®. There is no experience with patients receiving repeat courses of therapy with Retelies®.

Heparin and Retelies® are incompatible when combined in solution. If Retelies® is to be injected through an intravenous line containing heparin, a normal saline or 5% dextrose (D5W) solution should be flushed through the line prior to and following the Retelies® injection. Although the value of anticoagulants and antiplatelet drugs during and following administration of Retelies®

has not been studied, heparin has been administered concomitantly in most of the patients. Aspirin has been given either during and/or following heparin treatment.

▪Reteplase is not approved by the FDA for lysis of venous thrombus in DVT but is often used off-label. Catheter-directed infusion of 1U/h is maintained for 18-36 hours.

▪Reteplase is administered wildly in pulmonary embolism (PE) with the same dose which is administrated in MI.

Precautions:

Recent major surgery, cerebrovascular disease, recent GI or GU bleeding, Hypertension, acute pericarditis, hemostatic defects, severe thrombophlebitis, severe hepatic or renal dysfunction, currently receiving oral anticoagulants, diabetic hemorrhagic retinopathy.

Pregnancy:

Category C.

Lactation:

Undetermined.

Contraindications:

Active internal bleeding, history of cerebrovascular accident, recent intracranial or intraspinal surgery or trauma, intracranial neoplasm, arteriovenous malformation or aneurysm, bleeding diathesis or severe uncontrolled hypertension.

Adverse reactions:

Fever, nausea, vomiting, Bleeding, Reperfusion arrhythmias, Pain, redness, or swelling at the injection site.

Drug interactions:

Abciximab, aspirin, dipyridamole, heparin, warfarin, May increase the risk of bleeding.
Heparin and Reteplase are incompatible when combined in solution. If Reteplase is to be injected through an intravenous line containing heparin, a normal saline or 5% dextrose (D5W) solution should be flushed through the line prior to and following the Reteplase injection.

Packaging:

Retelies® kit is available as 2 single- use reteplase vials of 18 mg (10 units), 2 single –use diluent vials for reconstitution (10 ml sterile water for injection), 2 sterile 10 ml syringes, 4 sterile needles and a package of insert.

Reconstitution:

Each vial should be reconstituted with 10 mL of sterile water for injection (WFI) in the following manner:

Step 1: Remove the protective from one vial of Retelies®

Step 2: Withdraw 10 mL of sterile water for injection from the supplied container into a sterile 10 mL syringe with sterile needle provided in the kit.

Step 3: Clean the rubber cap of Retelies® vial and pierce the rubber cap with the syringe needle containing WFI and allow the WFI to transfer into the vial. Ensure all the WFI is transferred into the vial.

Step 4: Remove the needle and syringe from the vial. Gently swirl the contents of the vial for dissolution. Do not shake or vortex. Repeat gentle swirling till all the contents are dissolved.

Step 5: Allow the vial to stand for few seconds for dissipation of air bubbles.

Step 6: Attach a fresh sterile needle to the syringe and withdraw the reconstituted solution into the syringe.

Step 7: The 10 mL bolus is now ready for administration.

Step 8: After 30 minutes the same steps to be followed for the second bolus injection.

Storage:

Store between 2 to 8^{o}C and protect from light.

Do not use beyond the expiration date.

Keep out of reach of children.

Because reteplase contains no antibacterial preservatives, Preferably use solution immediately after preparation; when reconstituted as directed, the solution may be

used up to 4 hours, if stored in refrigerator (2 to 8 °C) or at controlled room temperature (less than 30°C).