METALYSE®

tenecteplase (rch) 50 mg

powder for injection

Boehringer Ingelheim

Dosage Instructions for Acute Myocardial Infarction

METALYSE should be administered on the basis of body weight, with a maximum dose of 50 mg (10,000 U).

The volume required to administer the correct dose can be calculated from the table below:

Patients' body weight category (kg)	METALYSE (U)	METALYSE (mg)	Corresponding volume of reconstituted solution (mL)
< 60	6,000	30	6
≥ 60 to < 70	7,000	35	7
≥ 70 to < 80	8,000	40	8
≥ 80 to < 90	9,000	45	9
≥ 90	10,000	50	10

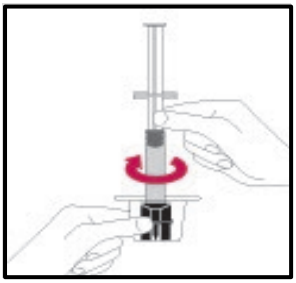
Instructions for Reconstitution & Handling

METALYSE should be reconstituted by adding the complete volume of Water for Injections (WFI) from the pre-filled syringe to the vial containing the powder for injection. Reconstitution can be performed using either the vial adapter or a needle. The reconstitution process using the vial adapter is described below:

1. Ensure that the appropriate vial size is chosen according to the body weight of the patient (see Dosage Instructions for Acute Myocardial Infarction).

2. Check that the cap of the vial is still intact.

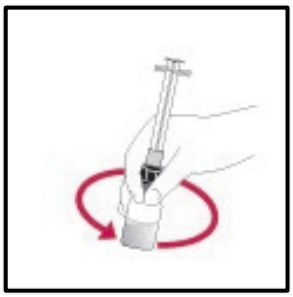
3. Open the box of the vial adapter.
Remove the flip-off cap from the vial.
Remove the tip-cap from the pre-filled syringe.



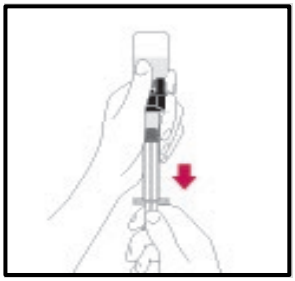
4. Immediately screw the pre-filled syringe securely onto the vial adapter tightly.

5. Penetrate the vial stopper in the middle with the spike of the vial adapter.

6. Add the WFI into the vial by pushing the syringe plunger down slowly to avoid foaming.

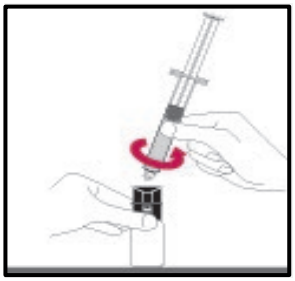


7. Keep the syringe attached to the vial adapter and reconstitute by swirling gently. The reconstituted preparation results in a colourless to pale yellow clear solution. Only clear solution without particles should be used.



8. Directly before the solution will be administered, invert the vial with the syringe still attached, so that the syringe is below the vial.

9. Transfer the appropriate volume of reconstituted solution of METALYSE into the syringe, based on the patient's weight (see Dosage Instructions for Acute Myocardial Infarction).



10. Unscrew the syringe from the vial adapter.

11. A pre-existing intravenous line, which has been used for administration of 0.9% Sodium Chloride solution only, may be used for administration of METALYSE. METALYSE should not be mixed with other medication, neither in the same injection-vial nor the same intravenous line (not even with heparin). Before dilution or administration, parenteral drug products should be visually inspected for particulate matter and discolouration prior to administration whenever solution and container permit.

12. METALYSE is to be administered as a single intravenous bolus in about 10 seconds. It should not be administered in a line containing dextrose as METALYSE is incompatible with dextrose solution.

13. The line should be flushed after METALYSE injection for proper delivery.

14. Any unused solution should be discarded.