

Dosage Instructions for Acute Ischaemic Stroke

METALYSE should be administered on the basis of body weight, with a maximum single dose of 25 mg (5,000 units) tenecteplase.

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

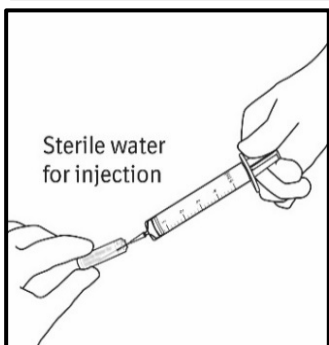
Patients' body weight category (kg)	Tenecteplase (mg)	Corresponding volume of reconstituted solution (mL)
< 60	15.0	3.0
≥ 60 to < 70	17.5	3.5
≥ 70 to < 80	20.0	4.0
≥ 80 to < 90	22.5	4.5
≥ 90	25.0	5.0

Instructions for Reconstitution & Handling

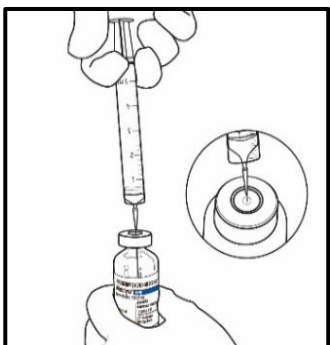
METALYSE should be reconstituted by adding 5 mL of sterile water for injections to the vial containing the powder for solution for injection using a needle and a syringe (not provided in the package).



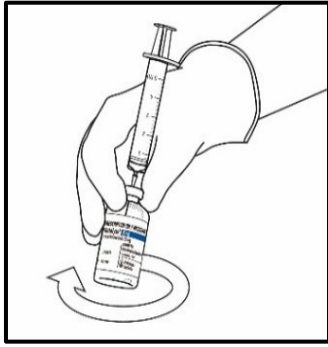
1. Remove the crimp cap from the vial.



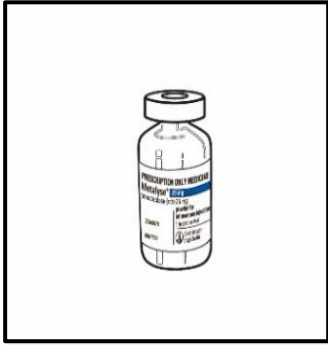
2. Fill a syringe with 5 mL of sterile water for injections.



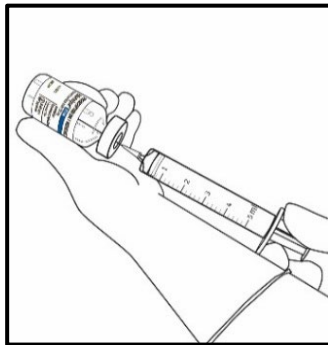
3. Penetrate the vial stopper in the middle with the needle. Add all the sterile water for injections into the vial by pushing the syringe plunger down slowly to avoid foaming.



4. Keep the syringe attached to the vial and reconstitute by swirling gently.



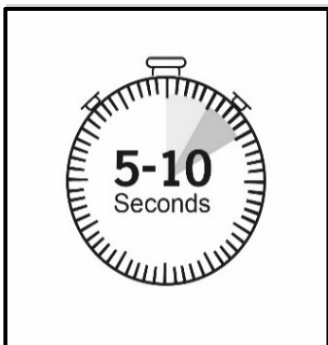
5. The reconstituted preparation is a colourless to pale yellow, clear solution. Only clear solution without particles should be used.



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

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

8. 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 drugs, neither in the same vial nor the same venous line.



9. METALYSE should be administered as a single dose to the patient, intravenously over 5 to 10 seconds. It should not be administered into a line containing dextrose as METALYSE is incompatible with dextrose solution.

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

11. Any unused solution should be discarded.