



The European Agency for the Evaluation of Medicinal Products  
*Post-authorisation evaluation of medicines for human use*

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**EMEA PUBLIC STATEMENT ON METALYSE (tenecteplase)**

**- IMPORTANCE OF CORRECT PRODUCT HANDLING:  
SYRINGE-VIAL ASSEMBLY -**

The European Medicines Evaluation Agency (EMEA) has been informed by Boehringer Ingelheim International GmbH, the Marketing Authorisation Holder (MAH) for Metalyse®, of four cases involving Metalyse® which suggest that the instructions for use of the product may not have been followed appropriately.

The active substance of Metalyse® is tenecteplase, an antithrombotic medicinal product. Metalyse® is indicated for the thrombolytic treatment of acute myocardial infarction.

The EMEA wishes to draw users' attention to the instructions for use detailed in the pictogram on the inner lid of the folding box - in particular to steps two, three and four. The vial and pre-filled syringe must be firmly connected by pressing down the syringe until a "**click**" is noticed. Failure to complete these steps correctly can cause the solvent to leak leading to an insufficient volume in the vial.

Users should check carefully there is no leakage of fluid as this could result in a patient receiving the incorrect dose.

Boehringer Ingelheim International GmbH is currently in the process of re-emphasising these crucial steps in the instructions for use and handling in the Summary of Product Characteristics (SPC) and in the instructions for use detailed in the pictogram on the inner lid of the folding box. Furthermore, the MAH has brought this problem to the attention of health care providers.

If you experience the problem described in this statement, please contact Boehringer Ingelheim International GmbH and/or the National Health Authorities in your country.

The EMEA thought it necessary to provide this information to the public. The SPC and labelling text will be updated in line with this information and will shortly be available in the European Public Assessment Report for Metalyse® on the EMEA website.

The current instructions for use and handling in the SPC and the instructions for use detailed in the pictogram on the inner lid of the folding box are attached for convenience.

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## **Instructions for use and handling in the SPC**

### **6.6 Instructions for use and handling, and disposal**

Metalyse should be reconstituted by adding the complete volume of water for injections from the pre-filled syringe to the vial containing the powder for injection.

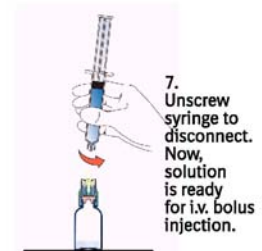
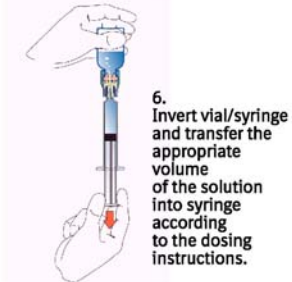
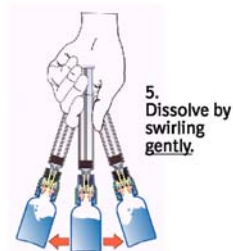
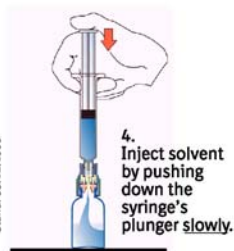
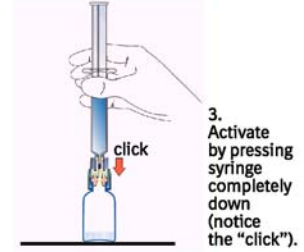
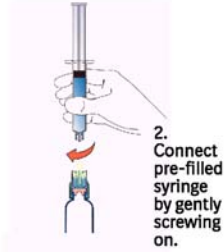
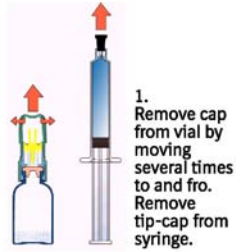
1. Ensure that the appropriate vial size is chosen according to the body weight of the patient.

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

2. Check that the cap of the vial is still intact.
3. Remove the vial cap and connect immediately the pre-filled-syringe to the Luer lock of the Bioset.
4. Activate by pressing the connected syringe down until a click sound confirms that it is engaged.
5. Add the water for injections into the vial by pushing the syringe plunger slowly down to avoid foaming.
6. Reconstitute by swirling gently.
7. 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. Withdraw into the syringe the appropriate volume of reconstituted solution of Metalyse, based on the patient's weight.
10. Disconnect the syringe from the vial.
11. Metalyse is to be administered to the patient, intravenously in about 10 seconds. It should not be administered in a line containing dextrose.
12. Any unused solution should be discarded.

## Instructions for use in the pictogram on the inner lid of the folding box

### Instructions for use



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