

Drug Alert

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Date: 25th August 2016

Our Ref: MDR 14-8/16

Dear Healthcare Professional,

Boehringer Ingelheim Limited

MA081/00101

**Actilyse 50mg powder and solvent for solution for
injection and infusion**

(alteplase)

Boehringer Ingelheim Limited (MAH) has received an increased number of complaints in the UK relating to the rubber stoppers being pushed into the vial during reconstitution using the supplied transfer cannula. This renders the vial unusable.

No similar complaints/cases have been received in Malta so far.

Users who experience this issue are asked to report it to Boehringer Ingelheim Medical Information on 01344 742579 or medinfo.bra@boehringer-ingelheim.com.

In some cases, handling errors may have contributed to the rubber stopper issue. Boehringer Ingelheim Limited has provided the attached handling instructions for the Actilyse transfer cannula to assist Healthcare Professionals, see Appendix 1.

Yours faithfully

Judit FEHÉR
Medicines Inspector

Appendix 1 - Actilyse transfer cannula handling instructions

Important Notice: Please always place the vial onto a solid surface when inserting the transfer cannula and insert pointed ends vertically in the centre of the vial stoppers.

Reconstitution should be carried out under aseptic conditions.

1. Open the blister pack of the transfer cannula and remove the protection cap from one end.
2. Remove the flip-off cap from the solvent vial. Put the vial on a flat surface.
3. Pierce the rubber stopper of the solvent vial by inserting the transfer cannula vertically in the center of the rubber stopper.
4. Remove the protection cap from the other end of the transfer cannula. Remove the flip-off cap from the powder vial.
5. Turn over the powder vial and pierce the rubber stopper of this vial upright and in the center with the spike of the transfer cannula, still inserted into the solvent vial.
6. Turn over the vials connected by the transfer cannula, so that the solvent vial is now on the top. The solvent flows into the powder vial on its own.
7. After the transfer of the solvent remove the empty solvent vial together with the transfer cannula and discard both appropriately.
8. The mixture should only be agitated gently until complete dissolution. Any vigorous agitation should be avoided to prevent foam formation.

