Healthcare Quality and Strategy Directorate
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The Scottish Government
Riaghaltas na h-Alba

LEGACY 2014
XX COMMONWEALTH GAMES
SCOTLAND

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

24 August 2016

Dear Healthcare Professional,

DRUG ALERT CLASS 4 no 11 2016 – Caution in Use

Please see the attached drug alert for onward transmission as below.
Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists

Please could Medical Directors forward this alert to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy and Medicines Division

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Pharmacy Level

Date: 24 August 2016 EL (16)A/11 Our Ref: MDR 70-08/16

Dear Healthcare Professional,

Boehringer Ingelheim Limited

Actilyse 20mg and 50mg powder and solvent for solution for injection and infusion (alteplase)

PL 00015/0120

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

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.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists for information.

Yours faithfully
S. Bax
Defective Medicines Report Centre
151 Buckingham Palace Road
London
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Telephone +44 (0)20 3080 6574

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.