



Safety Alert 002/12

15 March 2012

Product Recall - CSL Human Albumin – Batches Released from Quarantine (Albumex 4, Albumex 20)

Distributed to:

- Chief Executives
- Directors of Clinical Governance

Action required by:

- Chief Executives
- Directors of Clinical Governance

For response by:

- Directors of Clinical Governance

We recommend you also inform: (eg's)

- Directors of Anaesthesia & Surgery
- Directors of Emergency Medicine
- Directors of Intensive Care
- Directors of Neonatal Intensive Care
- Directors of Paediatric intensive Care
- Directors of Medical Services
- Medical staff

Deadline for completion of action

16 March 2012

Expert Reference Group

- Advice from TGA

Clinical Excellence Commission

Tel. 02 9269 5500
Fax. 02 926905599

Email:
quality@cec.health.nsw.gov.au

Internet Website:
<http://www.health.nsw.gov.au/quality/sabs>

Intranet Website
<http://internal.health.nsw.gov.au/quality/sabs/>

This Safety Alert supercedes SA001/12

Background

The Therapeutic Goods Administration (TGA) has informed NSW Ministry of Health on the 9 March 2012 that some stocks of CSL Human Albumin (4% and 20%) may be contaminated with Ethylene Glycol. Stocks were quarantined and TGA has informed the Ministry that certain batches of Albumin (4% and 20%) may be returned to use following testing.

Toxic levels of Ethylene Glycol can cause metabolic acidosis and renal failure.

Clinicians are advised to check the TGA website regularly regarding the release of stocks. It is being updated daily whilst stocks are being tested and released. The update on batches released and albumin available can be found on the TGA website at:

<http://tga.gov.au/safety/alerts-medicine-human-albumin-120310.html>

Clinicians wishing to be informed when new information is available from the TGA can subscribe to the TGA website update service at:

<http://tga.gov.au/newsroom/subscribe-tga-safetyinfo.html>

Albumin (4% and 20%) remains in tight supply and clinicians should carefully consider the need for use of Albumin as opposed to appropriate alternatives whilst the product is being tested and released from quarantine.

Mandatory actions for Local Health Districts/Networks

- **All LHD/LHNs are to inform relevant clinicians of the revised availability of Albumex 4, Albumex 20 stocks.**

References

- Advice from the TGA, "**TGA approves release of cleared batches of ALBUMEX**", dates 10 March 2012
<http://www.tga.gov.au/safety/alerts-medicine-human-albumin-120310.htm>

Action required by Local Health Districts /Networks

1. DCGs are to ensure that all relevant clinicians are aware of the REVISED availability of Albumex stocks.
2. Report on local actions to the CEC by 16 March 2012.