



# Department of Human Services

Incorporating: Health, Community Services, Mental Health, Senior Victorians and Housing

50 Lonsdale St  
GPO Box 4057  
Melbourne Victoria 3001  
DX210081  
[www.dhs.vic.gov.au](http://www.dhs.vic.gov.au)  
Telephone: 1300 650 172  
Facsimile: 1300 785 859

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## Urgent Recall Advice – Clexane

The Department of Human Services has received the following advice from the Office of Health Protection, Commonwealth Department of Health and Aging regarding the issue of contaminated Heparin, Clexane.

### Thursday, 24<sup>th</sup> April 2008.

- Australia's medicines regulator, the Therapeutic Goods Administration (TGA), has recalled five batches of the blood-thinning medicine Clexane due to the detection of an impurity in the affected batches.
- There have been no reports of adverse events in Australia associated with Clexane nor any other heparin based products – however, the TGA has decided to quarantine the affected batches of Clexane to guarantee the safety of all patients.
- Batch numbers are located on the side flap of the carton containing the Clexane. The affected batches are:

Clexane 20 mg Batch No. 02115

Clexane 40 mg Batch No. 04526

Clexane 80 mg Batch No. 08009

Clexane 100 mg Batch No. 01007

Clexane 100 mg Batch No. 01011

- The TGA has required testing of all heparin based products in Australia since March 2008. This followed several allergic reactions in the USA and Europe to another heparin based product found to have the same impurity.
- Clexane, and other heparin based products, are medicines, essential for patients for heart surgery, joint surgery, in patients with kidney failure and numerous other clinical conditions.
- At present there are alternative anticoagulants available for treating people who are currently using Clexane. The stocks of other heparins on the Australian market have been tested and are free of contaminant. They, and any uncontaminated batches of Clexane, can be used at this time.
- All doctors, pharmacists and state and territory health departments have been notified of the recall of the affected batches.
- A full analysis of the clinical implications of the recall is currently being undertaken by the TGA and the Commonwealth Department of Health and Ageing in collaboration with clinical experts, state and territory health authorities, the pharmacy community and medical colleges and associations.

- The Australian Health Protection Committee (AHPC), chaired by the Deputy Secretary of the Department of Health and Ageing, and the Chief Medical Officer are meeting daily with all state and territory Chief Health Officers, heads of clinical colleges, and the AMA.
- In line with prudent practice, this committee is developing contingency planning and clinical guidelines for the future safe use of heparin based products in consultation with clinical professionals. While it will not necessarily come to this, the recall, together with ongoing global supply problems, could result in a shortage of heparin based products in Australia. This could in turn have implications for surgery, and other clinical services.
- The TGA has met with all suppliers of heparin based products in Australia and is endeavoring to procure alternative supplies of heparin based products. It is also currently working with clinical experts from around the country; suppliers and international regulators, to determine the best way to ensure patients have safe access to heparin based products, and will keep the medical profession and consumers fully briefed as the situation unfolds.

## **Current Advice**

### **Patients**

Patients who use Clexane on prescription are advised to check with their doctor or pharmacist to determine if their supply of Clexane may have been affected. Patients should not discontinue treatment without consulting their doctor. After consulting their doctor they should return their supply of Clexane to their pharmacy if it is from one of the affected batches, and use the alternative anticoagulant prescribed by their doctor.

### **Doctors**

Doctors are asked to ensure their patients return any affected product to their pharmacy or clinic.

### **Pharmacists**

Pharmacists are advised to return any product dispensed from affected batches to the manufacturer, and to quarantine any affected product not yet dispensed on site pending further advice from the TGA.

### **Wholesalers**

Wholesalers are advised to quarantine affected batches of Clexane on site pending further advice from the TGA.

The detailed release associated with this recall is available from the following website <http://www.tga.gov.au/alerts/medicines/clexane.htm>

We will provide further information as it becomes available.

Authorised by: Director, Statewide Quality Branch