



- Please immediately bring to the attention of all doctors -

Date: 07 July 2008

Further Clexane Recall

Further to the previous precautionary recall of a number of Clexane batches, the Therapeutic Goods Administration (TGA) has requested that Sanofi-Aventis now recall an additional four batches of Clexane:

Strength (AUST R Batch No., Expiry Date, Dates Distributed)

Clexane (enoxaparin sodium) 80 mg/0.8mL injection syringe
(56710 08012, 09/2010, 23/11/2007)
Clexane (enoxaparin sodium) 80 mg/0.8mL injection syringe
(56710 08012A, 09/2010, 11/03/2008)
Clexane (enoxaparin sodium) 80 mg/0.8mL injection syringe
(56710 08014, 09/2010, 18/03/2008)
Clexane (enoxaparin sodium) 100 mg/1.0mL injection syringe
(56711 01010, 10/2010, 26/03/2008)

Reason for Action

The recall is a precautionary measure as these batches of Clexane have been manufactured from heparin containing low levels of the impurity, over sulphated chondroitin sulphate (OSCS) which has been associated with the occurrence of anaphylactic reactions in the US and Germany and has caused the previous recalls over the last few months. However, to date there continues to be no increase in reports of anaphylactic reactions in patients receiving Clexane in Australia.

Notification

Please ensure any patients under your care who are using Clexane 80 and 100 mg are informed of the recall of these additional batches. Patients with Clexane from an affected batch should return it to their pharmacy or clinic. Patients are to be advised not to discontinue their treatment without medical advice from their treating physicians. Patients who require ongoing anticoagulation should be advised to use unaffected batches of Clexane or alternative anti-coagulant therapy. Pharmacists have been advised that affected stock should be returned to the relevant supplier.

Return of stock

Please inspect any stock in your surgery/clinic and quarantine any units from the above-mentioned batches. The batch and expiry date are imprinted on one of the side flaps of the carton. The batch number is also present on each syringe. If you have already dispensed units of these batches to patients, please advise them of this recall as a priority. After you have quarantined the affected stock of Clexane at your premises, please return it to your source of purchase via their usual return processes. The returned stock should be identified as "RECALLED STOCK – CLEXANE".

Professor Paddy Phillips, Chief Medical Officer

PUBLIC HEALTH ALERT