

Thursday 1st May, 2008

Dear Pharmacist

Update on previous communication (sent 23rd April 2008) on Quarantine of 5 Clexane batches in Australia

I am writing to provide further clarification surrounding the quarantining/recall of five batches of Clexane (enoxaparin sodium) containing low levels of the impurity, over-sulphated chondroitin sulphate (OSCS).

As a precautionary measure, following a request from the Therapeutic Goods Administration (TGA), sanofi-aventis has undertaken a two-staged recall process involving these five affected batches of Clexane only, with Stage 1 being a quarantine of undispensed stock at the pharmacy level. Stage 2 will entail a second advice (target time 4 weeks or less) advising on either product return or other stock management action. Details regarding the 5 batches of affected stock are provided below.

Importantly, sanofi-aventis has reviewed its Global Safety Data Base adverse drug reaction reporting system and there has been no increase in the number of reported allergic reactions attributed to Clexane over the last 14 months. **Furthermore, there has been no increase in reports of allergic reactions or anaphylactic reactions in patients receiving Clexane in Australia during this time.** Whilst there have been heparin related adverse events reported in the US and in Germany, **Clexane has not been associated with any of these reported events.**

The following information may be of assistance during this period.

- Only stock from the 5 mentioned batches should be accepted for return from customers. **All other batches have been tested and do not contain any OSCS.**
- If a patient returns stock from one of the 5 affected batches please replace it with Clexane stock from an unaffected batch. Patients should not stop taking Clexane without medical advice.
- All stock currently being delivered to pharmacies (and since 24th April 2008) from sanofi-aventis are from unquarantined batches and do not contain any OSCS.
- Sanofi-aventis continues to have unaffected stock both in, and in-transit to, Australia and is working with wholesalers on a process for best distribution until a decision around the stage 2 recall is made with the TGA.
- If you have any stock from the 5 batches in your pharmacy please do not return it to sanofi-aventis but instead quarantine it at your pharmacy pending further advice from the TGA.

Sanofi-aventis contact details are as follows:

Customer Service	1800 640 791
Medical Information	1800 818 806

Clexane Batches Affected

Strength	AUST R	Batch No.	Expiry Date
Clexane enoxaparin sodium 20mg/0.2mL injection syringe	42965	02115	10/2010
Clexane enoxaparin sodium 40mg/0.4mL injection syringe	42962	04526	10/2010
Clexane enoxaparin sodium 80mg/0.8mL injection syringe	56710	08009	05/2010
Clexane enoxaparin sodium 100mg/1.0mL injection syringe	56711	01011	10/2010
Clexane enoxaparin sodium 100mg/1.0mL injection syringe	56711	01007	06/2010

Yours sincerely



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