

SHPA Website information: Clexane Recall

1. Why are batches of Clexane being quarantined?

The quarantine is being implemented as a precautionary measure due to the presence of low levels of an impurity in pure heparin associated with anaphylactic reactions in the US and Germany. This impurity is a worldwide heparin issue affecting a number of heparin products globally, not just Clexane.

In the context of this current global issue, sanofi-aventis has put in place an additional quality assurance procedure to allow the detection of the impurity, over-sulphated chondroitin sulphate (OSCS), in pure heparin used as starting material for the manufacture of enoxaparin sodium and in the finished product enoxaparin sodium (Clexane).

Following extensive testing worldwide using this procedure, sanofi-aventis has identified that a small number of batches of Clexane product containing low levels of the impurity, OSCS, have been released on the Australian market.

There has been no increase in reports of similar reactions in patients receiving Clexane in Australia.

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 2 years.

Following a request from the Therapeutic Goods Administration (TGA), sanofi-aventis is undertaking a two-staged recall process involving five affected batches of Clexane, with Stage 1 being a quarantine of stock, with no stock return.

2. Which batches of Clexane are 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 |

3. What should I do if I have affected Clexane stock?

Please inspect your stock and quarantine those units from the above-mentioned batches. The batch and expiry date are imprinted on one of the side flaps of the carton and on each individual syringe.

The Clexane recall is being conducted in two stages as requested by the TGA:

Stage 1 – Quarantine

Immediately quarantine affected stock on site. Store the quarantined stock away from the dispensary area, under appropriate storage conditions (< 25°C), pending the outcome of stage 2 of the recall. **Do not return affected stock.**

Pharmacies have been sent a Quarantine Form. Once affected stock of Clexane is quarantined at your premises, please return the form to sanofi-aventis. (Facsimile number: 1800 647 467)

Stage 2

A second advice (target time 4 weeks or less) will be provided advising you on either product return or other stock management action, depending on the evolving knowledge of the risk posed by the impurity.

4. What do I do if I have distributed Clexane to other pharmacies, hospitals or nursing homes?

- If you have supplied units of Clexane to other pharmacies or hospitals, please alert them to the need to quarantine affected batches.
- If you have dispensed units of Clexane to nursing homes or hostels please alert them to return affected batches to your pharmacy for replacement. Please send returned stock back to your supplier.

5. When will more information about the quarantine be available?

The TGA advise they are working with heparin manufacturers to develop the most effective strategies to allow safe supply of heparin products, and will keep health professionals and consumers fully briefed as the situation unfolds.

Sanofi-aventis is aiming to provide a second advice to you (target time 4 weeks or less) advising you on either product return or other stock management action depending on the evolving knowledge of the risk posed by the impurity.

6. What should I tell patients currently receiving Clexane?

Patients are to be advised not to discontinue their treatment without medical advice from their treating physician.

Patients requiring ongoing anticoagulation may require treatment with unaffected batches of Clexane or alternative treatment, in consultation with their treating physician.

Doctors have been advised to ask patients using affected batches to return stock to their pharmacy or clinic. This dispensed and returned stock should be sent back to your supplier.

If your patient is concerned or has experienced a problem with Clexane, please advise them to contact their treating physician for further advice.

7. What should I do if patients return Clexane to me?

Doctors have been advised to ask patients to check their stock for batch numbers and for those using affected batches to return supplies to the pharmacy or clinic for replacement with unaffected Clexane. Please send returned stock back to your supplier.

8. Can I still obtain Clexane/How will this affect the supply of Clexane?

Five batches of Clexane have been affected by this quarantine/recall. Sanofi-aventis are continuing to supply unaffected batches at present. If you have any questions relating to the availability of stock, please contact your supplier.

9. Sanofi-aventis contact details are as follows

Customer Service: 1800 640 791

Medical Information: 1800 818 806