

29 July 2008

TO: The Chief Pharmacist

Dear Chief Pharmacist

**RE: CLEXANE SUPPLY GOOD NEWS**

**Clexane enoxaparin sodium 80mg/0.8mL injection syringe AUST R 56710**

**Clexane enoxaparin sodium 100mg/1mL injection syringe AUST R 56711**

**Clexane enoxaparin sodium 40mg/0.4mL ampoules**

**Section s19A, TGA**

In our last communication letter dated 4 July, we indicated that whilst all other dosage strengths would be available from early July we were taking actions to ensure availability to patients of Clexane 80mg and 100mg strengths in Australia.

**Clexane enoxaparin sodium 80mg/0.8mL and 100mg/1mL injection syringes**

During the months of August and September you will receive US labelled 80mg/0.8mL and 100mg/1.0mL, brand named **Lovenox**, as an interim substitute for Clexane 80mg and 100mg pre-filled syringes. We anticipate that the period of supply of the US-labelled stock should not exceed 12 weeks. These presentations, which have been approved for supply under s19A of the Therapeutic Goods Act 1989, are not registered in Australia.

***US Stock Presentation and Packaging***

All aspects of these products, except the presentation and labelling, are identical to the current registered Clexane 80mg and 100mg pre-filled syringes. The US pre-filled syringes are designed with an automatic safety device shield. Administration information for the new device is provided in detail on the carton and in the package insert. As a result of this safety mechanism, the overall carton dimensions are larger.

***Packaging:***

		<b>Current Australian stock</b>	<b>US stock</b>
80mg	Size	75x55x145	169x66x138
	AUST R	56710	N/A
	EAN	9312319039673	300750622805
	<b>Name</b>	<b>Clexane</b>	<b>Lovenox</b>
	<b>SA Code</b>	<b>311525</b>	<b>318254</b>
100mg	Size	75x55x145	169x66x138
	AUST R	56711	N/A
	EAN	9312319039680	300750623005
	<b>Name</b>	<b>Clexane</b>	<b>Lovenox</b>
	<b>SA Code</b>	<b>311527</b>	<b>318255</b>

## Clexane 40mg ampoules

We have also secured a source of 40mg/0.4mL ampoules of uncontaminated Clexane to help maintain continued supply of heparin based products. This product, which has been approved for supply under s19A of the Therapeutic Goods Act 1989, is not registered in Australia.

This 40mg ampoule is manufactured for the German market and has German specific labelling, however is clearly marked as Clexane 40mg and the volume is 0.4mL. The Clexane 40mg ampoule does not require dilution or addition of a transport medium.

A sticker has been placed over the back panel of the pack, containing information for the Australian market, as shown below, and a copy of the Australian Product Information will be provided with each box:

40mg Amps	Size	82x38x100
	EAN	9319733001866
	Name	Clexane
	SA Code	317974



All aspects of this product, except the presentation and labelling, are identical to the current registered Clexane 40mg pre-filled syringe, including the same formulation and strength of enoxaparin sodium 40mg/0.4mL.

## How to Order New Formulations:

Clexane 80mg/mL and 100mg/mL should be ordered in the normal manner, through your hospital wholesalers. **If you have any issues re supply please contact sanofi-aventis Customer Service on 1800-640-791.**

Clexane 40mg ampoules should be ordered through your normal wholesaler. PLEASE NOTE AS THESE ARE AMPOULES AND NOT SYRINGES, AND A DIFFERENT PRESENTATION TO CLEXANE 40MG SUBCUT, THEY WILL HAVE A DIFFERENT PRODUCT CODE. THE SANOFI-AVENTIS CODE IS **317974**.

Please find attached the artwork of all presentations which you may find appropriate to use to inform your hospital staff of changes. Highlighted are the older Aventis presentations of the Clexane that are being replaced with new sanofi-aventis packaging. The presentations remain identical except for colour coded packs for greater ease of identification. Also shown are pictures of the interim US LOVENOX 80mg/0.8mL and 100mg/1.0mL and the Clexane 40mg/0.4mL ampoules.

If you have any queries regarding stock of Clexane, we recommend that you speak to your local sanofi-aventis Key Account Manager, who will be able to discuss the availability of Clexane.

Sanofi-aventis is committed to working with you and assisting with your hospital's educational needs regarding these products as required.

Thank you for your continued support.

Yours sincerely

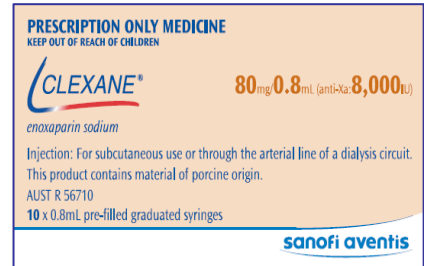
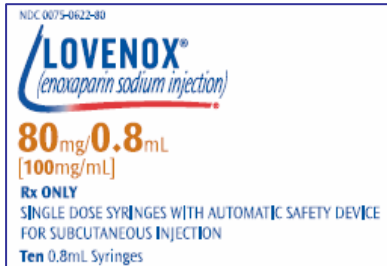
**Gordon Hirsch**  
Medical Director

**Clexane 80mg/0.8ml is temporarily being replaced  
by  
Lovenox 80mg/0.8ml from Aug-Oct 2008**

Lovenox artwork

Clexane current Aventis artwork

Clexane new sanofi-aventis artwork



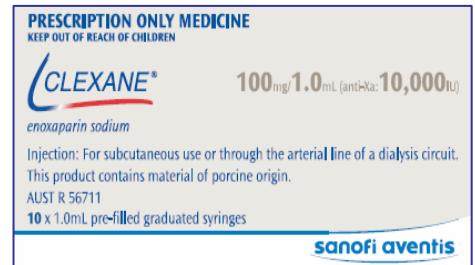
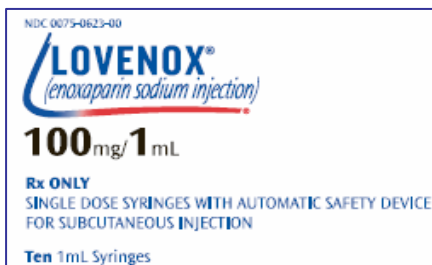
**Picture of Safety Syringe for Lovenox  
100mg**



Lovenox artwork

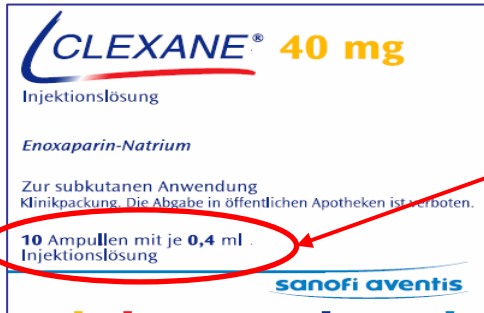
Clexane current Aventis artwork

Clexane new sanofi-aventis artwork

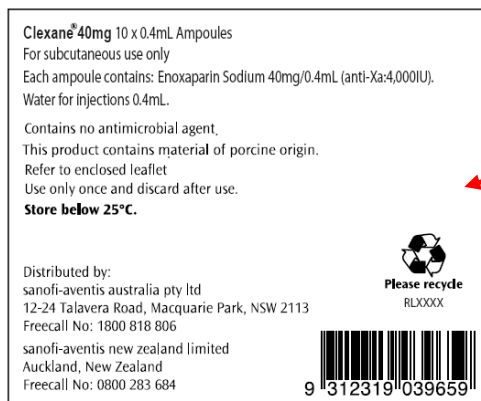


Please Note : Enoxaparin solution remains unchanged, the packaging has been updated or is from the USA and the Lovenox syringe has a safety lock

## Clexane 40mg Ampule (German Stock)



Please note this is an ampule



Clexane Australian Over labeling

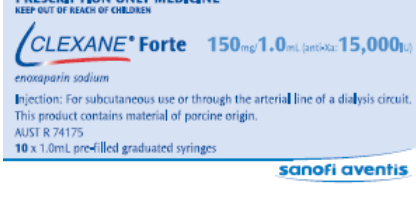
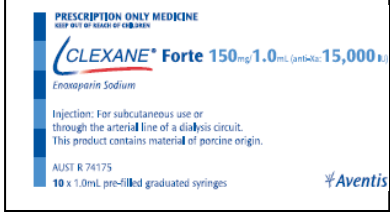
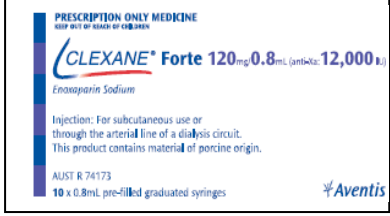
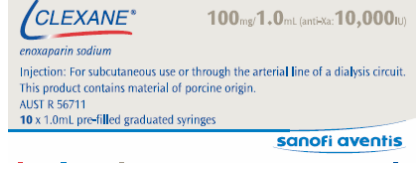
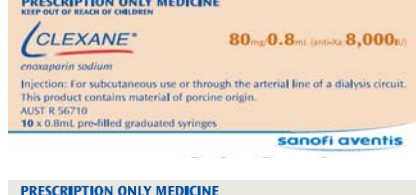
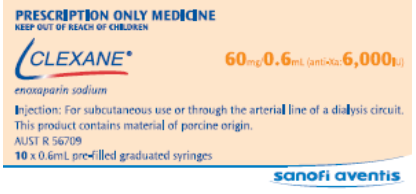
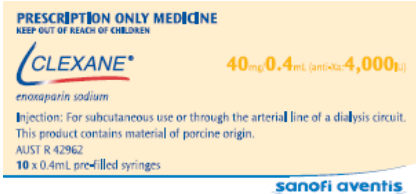
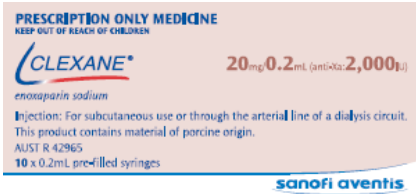
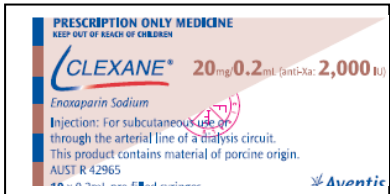


German 40mg Ampule

# Recent changes to Clexane packaging

Clexane current Aventis artwork

Clexane new sanofi-aventis artwork



Please Note : Australian Enoxaparin solution remains unchanged, the packaging has been updated