

# Availability of heparin based products (blood thinning medication) in Australia

## FAQs

**Q.** *What are heparin based products?*

**A.** Heparin based products are blood thinning medications that are used in patients for a range of conditions including kidney dialysis, heart surgery, as well as the treatment or prevention of other serious medical conditions such as blood clots or deep venous thromboses (DVT). Heparin products are given by injection, usually directly into the veins or the tissues.

**Q.** *Where does heparin come from?*

**A.** Heparin is a naturally occurring product made from animal intestines. The raw materials are used to make a range of heparin based products.

**Q.** *What has happened to the supply of heparin based products in Australia?*

**A.** Recently in the USA and Europe, some patients who received intravenous heparin experienced a life-threatening reaction. The reports of these reactions were investigated by the US Food and Drug Administration (FDA) who found that some of the heparin products were contaminated with a substance known as “over-sulphated chondroitin sulphate” or OSCS. Since then this contaminant has been shown to be the cause of these serious reactions.

Following these reports Australia’s medicines regulator, the Therapeutic Goods Administration (TGA), commenced testing of all supplies of heparin based products in Australia to determine if any had the contaminant. A small number of products were found to have the contaminant present and these products have been recalled from the market.

**Q.** *Why has the product Clexane been recalled?*

**A.** A small number of batches of enoxaparin (Clexane) were found to contain OSCS. Clexane with these batch numbers (see [TGA recall notice](#)) was recalled and quarantined by TGA. Supplies of other heparin based products currently on the market in Australia have been tested and are free of the contaminant.

**Q.** *Why was this recall necessary?*

**A.** While there have been *no* reports of adverse effects of the type reported in the USA in connection with the use of Clexane or any other heparin based products, a recall was undertaken as a precautionary measure, so that no patients are put at undue risk at this time.

**Q.** *How many people have had these serious adverse events with Clexane in Australia?*

**A.** None. There have not been any adverse events of the type seen in the US anywhere in the world reported with the use of Clexane.

**Q.** *I am using Clexane. Should I stop using it?*

**A.** No. It is very important that you continue to use Clexane or another blood thinning agent if it has been prescribed for you. If you have Clexane in your possession and you have not already done so you should check with your doctor or pharmacist to determine if your Clexane is from a contaminated batch.

**Q.** *What should I do if I have taken contaminated Clexane?*

**A.** If you believe you may have previously taken Clexane from a contaminated batch you should not be alarmed. The serious adverse reactions of the kind reported in the US were only seen with contaminated heparin given directly into the veins whereas Clexane is usually given as an injection into the tissues. However if you have had any adverse reaction that you think may be linked to your use of Clexane, you should ask your doctor to report it to the TGA's Adverse Drug Reactions Unit at the following web address <https://www.tgasime.health.gov.au/SIME/ADRS/ADRSRepo.nsf?OpenDatabase> or via email to [adrac@tga.gov.au](mailto:adrac@tga.gov.au)

**Q.** *I have had Clexane in the past. Am I at risk of a serious reaction now?*

**A.** No. All reported reactions have occurred immediately following the injection of the heparin based product. Serious adverse reactions have not been reported anywhere in the world from the use of Clexane.

**Q.** *What other blood thinning products are available?*

**A.** There are a range of other medications that may be used as blood thinners, depending on the circumstances. There are oral medications such as warfarin (Coumadin/Marevan), clopidogrel (Plavix/Iscover) and dipyridamole (Persantin). Other injected medications include dalteparin (Fragmin) and fondaparinux (Arixtra). In addition other forms of heparin have found to be clear of the contaminant and may continue to be used.

**Q.** *Are all blood thinning products affected?*

**A.** No. Oral blood thinning products like warfarin are not affected by this contamination. After thorough searching, no contamination was found in any other forms of blood thinners available in Australia other than Clexane at the current time.

**Q.** *If only a small amount of Clexane has been recalled, why is there concern about a possible shortage of heparin based products?*

**A.** Clexane is a product that is used very widely in the Australian health care system, and while only a small amount has been recalled, there is a worldwide problem of contaminated Clexane stocks. This, together with some uncertainty about how long it will take for normal volumes of uncontaminated products to become available again, could potentially lead to shortages of some products.

**Q.** *What is the Government doing about this potential shortage?*

**A.** The Government, through the TGA, is working to get alternative supplies of heparin based products. A group of experts has been called together to develop clinical guidelines (link to Guidelines) based on the best available medical evidence to ensure that patients continue to receive appropriate heparin based products according to their clinical need. The guidelines will help to identify those patients who may be safely treated with medications other than Clexane.

**Q.** *How long will the shortage last?*

**A.** The world may see shortages of various heparin products for some time. However, the Guidelines will assist in ensuring that with the careful use of available supplies, the effects of any possible shortages can be minimized until normal heparin supply levels can once again be restored.

**Q.** *I am having surgery next week. Should I postpone?*

**A.** No. There are many different methods to reduce the risks of blood clots when people undergo surgery. Your doctor can explain these to you.