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Information Exchange System

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Important safety update on lepirudin (Refludan) following reports of fatal anaphylactic reactions

The European Medicinal Products Evaluation Agency (EMEA) and its Scientific Committee have received seven recent reports of severe anaphylactic reactions in patients receiving lepirudin (Refludan), a recombinant hirudin approved as an anticoagulant in adult patients with heparin-associated thrombocytopenia (HAT) type II with thromboembolic disease mandating parenteral antithrombotic treatment. Six of the reports involved re-exposure to lepirudin (Refludan); the patient died in five of these cases.

The EMEA has issued a public statement highlighting the following important safety information on lepirudin (Refludan):

- Lepirudin (Refludan) may cause allergic reactions including anaphylaxis. Anaphylactic reactions resulting in fatality have been reported in patients re-exposed to lepirudin (Refludan) in a second or subsequent treatment course. Since these anaphylactic reactions are immune-mediated, patients with recent exposure to lepirudin (Refludan), hirudin or hirudin analogues may be at increased risk.

- Physicians must check for previous exposure to lepirudin (Refludan), hirudin or hirudin analogues while considering treatment with lepirudin (Refludan); alternative treatment options should be considered before taking the decision to re-expose a patient to lepirudin (Refludan).

- Treatment with lepirudin (Refludan) should be undertaken only in a setting where medical assistance is readily available, with access to treatment for anaphylactic shock.

- Patients should be informed if treated with lepirudin (Refludan), with instructions to inform future prescribers of the fact.

Lepirudin (Refludan) was authorised in the European Union (EU) in 1997 and is currently marketed within the EU in Greece, Austria, UK, Ireland, Finland, Spain, Belgium, France and Germany.

Reference:
Facsimile message from the European Medicinal Products Evaluation Agency (EMEA) dated 25 October 2002.