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Questions and answers on Lovenox and associated names (enoxaparin, solution for injection)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 15 December 2016, the European Medicines Agency completed a review of Lovenox and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Lovenox in the European Union (EU).

What is Lovenox?

Lovenox is an anticoagulant medicine (a medicine to prevent blood clots) used in adults to prevent and treat conditions associated with blood clots such as deep vein thrombosis (where the clot develops in a deep vein, usually in the leg), as well as unstable angina (a severe type of chest pain caused by problems with the blood flow to the heart) and certain types of myocardial infarction (heart attack);

Lovenox contains the active substance enoxaparin. It is available as vials, ampoules, prefilled syringes and pens and is given by injection under the skin or into a vein.

Lovenox is available in all EU countries. It is also available under other trade names: Clexane, Clexane T, Clexane Forte, Klexane, Qualiop, Enoxaparin Sanofi and Enoxaparine Sanofi. The company that markets these medicines is Sanofi.

Why was Lovenox reviewed?

Lovenox is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Lovenox was identified as needing harmonisation by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

On 12 November 2015, France referred the matter to the CHMP in order to harmonise the marketing authorisations for Lovenox in the EU.

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What are the conclusions of the CHMP?

The CHMP, in light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

The CHMP agreed that the strength of the active substance enoxaparin will now be expressed both in international units (IU) and in milligram (mg) throughout the product information.

4.1 Therapeutic indications

The CHMP agreed that Lovenox can be used for the following uses:

- to prevent venous thromboembolism (blood clots that form inside the veins, obstructing blood flow), especially in patients who are having surgery or who are at greater risk of clots because they have reduced mobility due to illness;
- to treat conditions associated with blood clots such as deep vein thrombosis (where the clot develops in a deep vein, usually in the leg) or pulmonary embolism (clot in a blood vessel supplying the lung);
- to treat unstable angina (a severe type of chest pain caused by problems with the blood flow to the heart);
- to treat certain types of myocardial infarction (heart attack);
- to prevent clots forming when blood is circulated through a haemodialysis machine to remove toxic substances.

4.2 Posology and method of administration

For the treatment of deep vein thrombosis and pulmonary embolism, the CHMP also clarified that the dose regimen of 150 IU/kg (1.5 mg/kg) given once daily should only be used only in uncomplicated patients who have a low risk of a further venous thromboembolism. Patients at higher risk should be given 100 IU/kg (1 mg/kg) twice daily.

The regimen should be selected by the physician based on an individual assessment including evaluation of the thromboembolic risk and of the risk of bleeding.

This section was also updated to reflect that outside its approved use in haemodialysis Lovenox is not recommended in patients with end stage kidney disease. A table with dosing recommendations in this group was included.

4.3 Contraindications

A contraindication that existed in some EU member states for use in patients with severe kidney impairment was removed.

The Committee also harmonised other sections of the SmPC including sections 4.4 (special warning and precautions), 4.5 (interaction with other medicinal products and other forms of interaction), 4.6 (fertility, pregnancy and lactation), 4.7 (effects on ability to drive and use of machines) and 4.8 (undesirable effects).

The amended information to doctors and patients is available here.

The European Commission issued a decision on this opinion on 9/03/2017.