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EPAR summary for the public

Thorinane

enoxaparin sodium

This is a summary of the European public assessment report (EPAR) for Thorinane. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Thorinane.

For practical information about using Thorinane, patients should read the package leaflet or contact their doctor or pharmacist.

What is Thorinane and what is it used for?

Thorinane is an anticoagulant medicine (a medicine to prevent blood clots). It is used in adults for the following:

- 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 are bedridden 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);
- 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.

In the treatment of unstable angina and heart attack Thorinane is given with aspirin (acetylsalicylic acid).

The active substance in Thorinane is enoxaparin sodium.

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Thorinane is a 'biosimilar medicine'. This means that Thorinane is highly similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Thorinane is Clexane. For more information on biosimilar medicines, see the question-and-answer document here.

How is Thorinane used?

Thorinane is available as a solution for injection in pre-filled syringes. It is usually given as an injection under the skin although in the treatment of a type of heart attack called acute ST-segment elevation myocardial infarction (STEMI) it is first given as an injection into a vein, and to prevent clots in haemodialysis machines it is injected directly into the tube carrying the blood. The dose and how long the medicine is given for, as well as whether it is given with other medicines, depend on the condition to be prevented or treated. Doses must be adjusted in patients with severely reduced kidney function.

The medicine can only be obtained with a prescription. For further information, see the package leaflet.

How does Thorinane work?

When blood clots develop inside blood vessels they may restrict the blood flow to the organs, including the heart. The active substance in Thorinane, enoxaparin, is one of a group of anticoagulant medicines called 'low-molecular weight heparins'. Enoxaparin increases the effect of antithrombin III, a natural substance that controls the blood's clotting factors and helps prevent blood from clotting inside the body. This helps to stop the formation of new blood clots and control existing ones.

What benefits of Thorinane have been shown in studies?

Extensive laboratory studies comparing Thorinane with Clexane have shown that Thorinane is highly similar to Clexane in terms of structure, purity and biological activity.

In addition, a study in 20 healthy subjects has shown that the same doses of the two products given by injection under the skin produced similar effects on blood clotting factors, using various measures that reflect the way the medicine works in the body.

The company also provided information from published studies showing the benefits of enoxaparin in preventing and treating blood clots.

What are the risks associated with Thorinane?

The most common side effect with Thorinane (which may affect more than 1 in 10 people) is haemorrhage (bleeding); serious bleeding occurred in around 4 people in 100 given Thorinane to prevent blood clots during surgery. In addition, increased levels of liver enzymes in the blood (a sign of possible liver problems) are very common (may affect more than 1 in 10 people).

For the full list of all side effects reported with Thorinane, see the package leaflet.

Thorinane must not be used in patients with existing major bleeding, severe disorders of blood clotting, or with conditions that increase the risk of, or from, bleeding, such as stomach ulcers or stroke. For the full list of restrictions, see the package leaflet.

Why is Thorinane approved?

Studies have shown that Thorinane has a highly similar structure and biological activity to Clexane and has the same effect on blood clotting factors. The safety profiles of the two medicines were also considered similar, based on laboratory testing.

Therefore, the Agency's Committee for Medicinal Products for Human Use (CHMP) considered that there are no clinically meaningful differences between Thorinane and Clexane in terms of effectiveness and safety and took the view that, as for Clexane, the benefit outweighs the identified risk. The Committee recommended that Thorinane be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Thorinane?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Thorinane have been included in the summary of product characteristics and the package leaflet.

Other information about Thorinane

The European Commission granted a marketing authorisation valid throughout the European Union for Thorinane on 15 September 2016.

The full EPAR for Thorinane can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Thorinane, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2016.