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Inhixa (*enoxaparin sodium*)

An overview of Inhixa and why it is authorised in the EU

What is Inhixa and what is it used for?

Inhixa is an anticoagulant medicine (a medicine that prevents blood clots) used in adults for:

- preventing 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;
- treating deep vein thrombosis (DVT, where the clot develops in a deep vein, usually in the leg) and pulmonary embolism (PE, a clot in a blood vessels supplying the lungs);
- treating DVT and PE in patients with active cancers, and preventing these clotting problems from occurring again;
- treating unstable angina (a severe type of chest pain caused by problems with the blood flow to the heart);
- treating certain types of myocardial infarction (heart attack);
- preventing clots forming when blood is circulated through a haemodialysis machine to remove toxic substances.

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

Inhixa contains the active substance enoxaparin sodium and is a 'biosimilar medicine'. This means that Inhixa is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Inhixa is Clexane. For more information on biosimilar medicines, see here.

How is Inhixa used?

Inhixa 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 more information about using Inhixa, see the package leaflet or contact your doctor or pharmacist.

How does Inhixa work?

When blood clots develop inside blood vessels they may restrict the blood flow to the organs, including the heart. The active substance in Inhixa, 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 Inhixa have been shown in studies?

Laboratory studies comparing Inhixa with Clexane have shown that the active substance in Inhixa is highly similar to that in 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.

Because Inhixa is a biosimilar medicine, the studies on effectiveness and safety of enoxaparin carried out with Clexane do not all need to be repeated for Inhixa.

What are the risks associated with Inhixa?

The safety of Inhixa has been evaluated, and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine Clexane.

The most common side effect with Inhixa (which may affect more than 1 in 10 people) is haemorrhage (bleeding); serious bleeding may occur in around 4 in 100 people given Inhixa 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 side effects reported with Inhixa, see the package leaflet.

Inhixa 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 Inhixa authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Inhixa has a highly similar structure, purity 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.

All these data were considered sufficient to conclude that Inhixa will behave in the same way as Clexane in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was

that, as for Clexane, the benefits of Inhixa outweigh the identified risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Inhixa are continuously monitored. Suspected side effects reported with Inhixa are carefully evaluated and any necessary action taken to protect patients.

Other information about Inhixa

Inhixa received a marketing authorisation valid throughout the EU on 15 September 2016.

Further information on Inhixa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/inhixa

This overview was last updated in 04-2022.