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Heparin Sintetica® (active substance: heparin sodium)

First authorisation in Switzerland: 20 December 2021

Medicinal product (solution for infusion) for the treatment of thromboembolic disorders and for administration after thrombolytic therapy

About the medicinal product

The medicinal product Heparin Sintetica, containing the active substance heparin sodium, is used to treat thromboembolic[1] disorders of all causes and at any site. Heparin Sintetica is also used to inhibit clotting during extracorporeal circulation[2] and haemodialysis (blood filtration).

Unfractionated heparin (UFH) is a natural mixture of amino polysaccharides (glycosaminoglycans) of varying chain lengths obtained from animal tissues.

Mode of action

Heparin sodium inhibits blood clotting by "neutralising" two key enzymes[3] involved in coagulation (thrombin [factor IIa] and factor Xa).

[1] Thromboembolism: a thromboembolic event is caused by a blood clot (thrombus) that blocks a site in the bloodstream or that is transported elsewhere in the bloodstream (embolus) and blocks another vessel (embolism).

[2] Extracorporeal circulation: extracorporeal circulation is the circulation of blood outside the body, e.g. in order to temporarily replace the function of organs.

[3] Enzymes: enzymes are proteins that act as biocatalysts, controlling and accelerating biochemical reactions in the body.

Use

Heparin Sintetica, containing the active substance heparin sodium, is a prescription-only medicine.

It is available as a vial containing 48 ml of solution for infusion with 20,000 I.U.[4] of heparin sodium and is administered intravenously.

The standard daily dose is 10,000 I.U. The dosage of Heparin Sintetica is determined individually and depends on various factors (e.g. nature and course of the illness, patient's weight and age and possible adverse reactions).

The dosage must be high enough, since the process of clot formation can progress with the continued risk of an embolism if the dose is too low.

The treatment with Heparin Sintetica is monitored by checking the clotting status at regular intervals and adjusting the dosage if necessary.

Efficacy

Since the efficacy of unfractionated heparins (UFH) is well known, no additional clinical studies have been conducted with Heparin Sintetica.

The efficacy was predominantly assessed on the basis of the scientific literature and laboratory analyses carried out with Heparin Sintetica. These showed that the effect of Heparin Sintetica is comparable with that of existing heparin products.

A review of the mainly literature-based documentation did not reveal any evidence to suggest that the efficacy and safety profile of Heparin Sintetica differs from that for existing known heparin products.

The laboratory analyses support the assumption of comparability.

Precautions, undesirable effects & risks

Heparin Sintetica must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common adverse reactions involve the clotting system. The anticoagulant effect of heparin increases the risk of bleeding during treatment.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Based on the review of the submitted documentation on Heparin Sintetica, it was concluded that, in terms of efficacy and safety, Heparin Sintetica is comparable with other unfractionated heparins that are currently available on the Swiss market.

Taking all the risks and precautions into account, and based on the available data, the benefits of Heparin Sintetica outweigh the risks.

Swissmedic has therefore authorised the medicinal product Heparin Sintetica with the

[4] I.U.: the abbreviation I.U. is short for International Unit. I.U. is a unit of measurement for certain substances that are measured not according to their weight but based on their function or activity. Examples of such substances include various vitamins and insulin.

active substance heparin sodium for the treatment of thromboembolic disorders.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Heparin Sintetica®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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