LOW MOLECULAR WEIGHT HEPARIN

PRODUCT PROFILE

SYNTEX S.A.
Luis De Sarro 501 - (B1838DQK) – Luis Guillón – Buenos Aires – Argentina – Tel./Fax: (54 11) 4367-6100 syntex@syntexar.com – www.syntexar.com

Brief introduction

Low Molecular Weight Heparins (LMWH) were first introduced into clinical uses in the middle 1980 decade and are now among the therapeutics of choice for the prevention and treatment of thrombosis (1) (2)
It is well-known that LMWH is an antithrombotic agent offering three advantages over the unfractioned Heparin (UFH):

- Reduced bleeding risk
- Prolonged half-life in bloodstream
- Reduced interference with platelets

Currently, there are at least eight LMWH with their own individual International Non – Proprietary Name (INN), as approved by World Health Organization (WHO) (3), an indication that the active ingredient for these different products is not the same.
The corresponding European Pharmacopeia monographs shows the diversity of the manufacturing methods for different LMWH, and the heterogeneity in their physicochemical characteristics and anticoagulant – antithrombotic profiles, thus defining one by one such substances

Uses

Antithrombotic agent.
Prevention and treatment of thrombosis.

Production

Syntex LMWH is produced by chemical radical fragmentation of pharmaceutical grade Heparin (UFH), according with proprietary methods, well described in US Patent 4977250, Europ. Patent 268885 and extensions, AR Pat 243540.

It is produced in Syntex S.A. at full-industrial scale.

Syntex LMWH is being commercialized in Japan market under the trade name “Parnaparin ITO” (Initiative for Life Sciences – ILS – Otsuka Group) (“Mini-Hepa”, ILS-Otsuka Group) since 2002 up to date.
Syntex LMWH was registered, at that time in Japan, under the status of “Essentially Similar”, so recognized by Japanese National Health Authorities.

In 2008, Syntex´s manufacturing site had been successfully audited by Japanese Sanitary Authorities (PMDA).

From the beginning, “Mini-Hepa” (ILS – Otsuka) was used for hem dialysis prescription, without doubt, one of the most exigent uses for a LMWH and no undesirable phenomena of intra-catheter blood coagulation ever took place.

So, Syntex´s LMWH, as per a “generic” form of Parnaparin Sodium (INN) is accounting ten years in routinely pharmacovigilance.

Specifications

Syntex´s LMWH fully complies with EP 7.0 general monograph for LMWH and JP 16° Edition for Parnaparin Sodium (excluding definition of preparation method, naturally).

Packaging

Bulk powder in double polyethylene bags contained in lined drums.

References

(1) www.nice.org.uk/nicemedia/pdf/VTEconsultations NICE Guideline. pdf

(2) KEARON, C et al; ANTITHROMBOTIC and TRHOMBOTILYTIC THERAPIES 8° Ed; ACCP Guidelines: Antithrombotic therapy for venous thromboembolic disease. CHEST, 2008; 133, 454S – 545S

(3) www.who/medicined/services/in/en/

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