

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0046/036/003

Case No: 2007761

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Leo Laboratories Limited

Cashel Road, , Dublin 12, Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Heparin (Mucous) Injection B.P. 25,000 Units/ml

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **14/03/2006** until **31/03/2008** .

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

4 CLINICAL PARTICULARS

4.3 Contraindications

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

4.6 Pregnancy and lactation

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

5 PHARMACOLOGICAL PROPERTIES

6 PHARMACEUTICAL PARTICULARS