IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0261/035/001
Case No: 2061659

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

Organon Laboratories Limited

Cambridge Science Park, **Milton Road**, **Cambridge CB4 0FL**, **United Kingdom**

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

Sterilised Water for Injection

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 **23/08/2009**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sterilised Water for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains Water for injections.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solvent for Parenteral use
Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the reconstitution, dilution and making up of appropriate drugs and for use as an irrigant.

4.2 Posology and method of administration

Recommended Dosage

As appropriate to the reconstituted drug.

Route of administration

As appropriate to the reconstituted drug.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

Each unit should be discarded after a single use.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

This solvent does not present any hazard to the pregnant woman, to the foetus or to the breast-fed child.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No special particulars.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Store below 30^{o}C.

6.5 Nature and contents of container

1 ml, 2 ml and 5 ml ampoule of uncoloured, clear Type I glass (Ph.Eur.).

Cartons contain 1, 5, 10, 20 or 50 ampoules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Water for injections can be used for reconstitution of freeze-dried products.

7 MARKETING AUTHORISATION HOLDER

Organon Laboratories Ltd.
Cambridge Science Park
Milton Road
Cambridge
CB4 0FL
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 261/35/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 August 1999

Date of last renewal: 23 August 2009

10 DATE OF REVISION OF THE TEXT

September 2009