

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA1175/009/001

Case No: 2043167

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

Medlock Medical Ltd

Tubiton House, Medlock Street, Oldham, OL1 3HS, United Kingdom

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

Sterets Pre-Injection Swabs %v/v Impregnated Dressing

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 **23/04/2008**.

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

1 NAME OF THE MEDICINAL PRODUCT

Sterets Pre-Injection Swabs 70% v/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each swab is impregnated with an aqueous solution of Isopropyl Alcohol 70% v/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Impregnated dressing.

Impregnated dressing in a colourless to pale straw solution presented in a disposable sachet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For pre-injection site cleansing.

4.2 Posology and method of administration

For topical administration.

To be used as directed by a physician.

4.3 Contraindications

Use in patients hypersensitive to the active ingredient.

4.4 Special warnings and precautions for use

1. Side effects include local irritation and dryness. Allergic eczema has also been reported.
2. The sachet should not be used if damaged before opening.
3. Avoid contact with eyes or broken skin.
4. Products containing alcohol should not be brought into contact with some vaccines and skin test injections (patch tests).

4.5 Interaction with other medicinal products and other forms of interaction

Alcohol should not be brought into contact with some vaccines and skin test injections (patch tests). If in doubt, consult the vaccine manufacturers literature.

4.6 Pregnancy and lactation

No special precautions required.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Local irritation and dryness. Allergic eczema has also been reported.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

70% isopropyl alcohol has disinfectant properties and is appropriate for swabbing onto cleanse and lower the skin bacteriological count prior to injections.

5.2 Pharmacokinetic properties

There is little absorption of isopropyl alcohol through the intact skin, pharmacokinetic particulars are not applicable.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water.
Absorbent viscose pad.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Do not store above 25°C. Store sachets in the outer carton. Keep away from naked flames.

6.5 Nature and contents of container

Printed aluminium foil laminated sachets of coated paper/polyethylene/aluminium foil/surlyn, the surlyn layer innermost. The sachets are in strips of two, separated by sections.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Medlock Medical Ltd
Tubiton House
Medlock Street
Oldham
OL1 3HS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 1175/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 April 1993

Date of last renewal: 23 April 2008

10 DATE OF REVISION OF THE TEXT

December 2008