

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA1175/005/001

Case No: 2032104

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, England

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

Manusept Antibacterial Hand Rub 0.5%w/v + 70%v/v Cutaneous Solution

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 **23/04/2007**.

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

Manusept Antibacterial Hand Rub 0.5% w/v + 70% v/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 5mg Triclosan

Each ml contains 0.7ml Isopropyl Alcohol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution

A clear, colourless cutaneous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For skin disinfection prior to surgery, injection and venepuncture.

4.2 Posology and method of administration

Topical.

Hand disinfection:

Apply 3ml to washed hands. Rub vigorously into hands until dry.

Pre-operative hand disinfection:

Apply 5ml to washed hands and forearms. Rub vigorously until dry. Repeat.

Disinfection prior to injection or venepuncture:

Apply a small quantity to cotton wool swab. Rub vigorously until dry.

4.3 Contraindications

Hypersensitivity to triclosan or to any of the excipients.

4.4 Special warnings and precautions for use

Avoid contact with the eyes (or mucous membranes).

Do not apply to broken skin.

Should sensitivity develop, discontinue use.

Do not use in the vicinity of naked flames.

For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

There have been isolated reports of contact dermatitis with the use of Triclosan.

4.9 Overdose

If swallowed, gastric aspiration and lavage avoiding pulmonary aspiration, apomorphine should not be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D08AE04; D08AX05: Antiseptics and disinfectants.
Triclosan is bactericidal. Isopropyl alcohol is bactericidal.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl myristate
Deionised water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 3 years.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

High density polyethylene bottles with compression moulded screw cap with steran faced pulpboard wads.
Polypropylene screw cap.
Sizes: 100 ml, 250 ml, 500 ml, 5000 ml.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Medlock Medical Ltd
Tubiton House
Medlock Street
Oldham
OL1 3HS
UK

8 MARKETING AUTHORISATION NUMBER

PA 1175/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 April 1992

Date of last renewal: 23 April 2007

10 DATE OF REVISION OF THE TEXT

July 2007