

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0979/004/001

Case No: 2051147

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

Reckitt Benckiser Ireland Ltd

7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

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

Dettol Antiseptic Cream Chloroxylonol 0.3%w/w Triclosan 0.3%w/w Edetic Acid 0.2%w/w

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 **23/10/2008**.

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

Dettol Antiseptic Cream
Chloroxylenol 0.3% w/w
Triclosan 0.3% w/w
Edetic Acid 0.2% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cream containing:		
Chloroxylenol	0.30	% w/w
Triclosan	0.30	% w/w
Edetic acid (as the potassium salt)	0.20	% w/w

Contains Cetostearyl Alcohol (a constituent of Emulsifying Wax)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

A white, water-miscible cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antiseptic for the topical treatment of skin injuries.

4.2 Posology and method of administration

For the topical application to the skin.

Adults and children: After thorough cleansing, apply in small amounts directly on the skin as required.

There is no indication that dosage need be modified for the elderly.

4.3 Contraindications

Known hypersensitivity to the active ingredients

Allergic skin reactions, dermatitis, eczema or other skin complaints.

4.4 Special warnings and precautions for use

If there is no improvement or the condition is aggravated, consult the doctor.

Treatment should be terminated if irritation develops. In the event of any irritation of sensitive skin, wash with

lukewarm water.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There is inadequate evidence of the safety of the drug in human pregnancy and lactation, but there has been wide use in humans without apparent ill consequence. Animal studies have shown no hazard. If drug therapy is needed in pregnancy this drug can be used if there is no safer alternative.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

4.9 Overdose

It is unlikely that a sufficient volume of the cream could be ingested to cause any medical problems. In the event of accidental eye contact, wash with lukewarm water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chloroxylenol is an antiseptic agent whose activity is principally against *Streptococci*, but also has some activity against *Staphylococci*. Triclosan exhibits bacteriostatic activity against a wide range of Gram positive and Gram negative organisms. These active ingredients are themselves resistant to the *Pseudomonas* species, but inclusion of EDTA potentiates their activity against this organism.

5.2 Pharmacokinetic properties

Animal studies have shown that following dermal application chloroxylenol is rapidly absorbed (C_{max} = 1-2 hours), extensively metabolised and excreted via the kidney with almost complete elimination within 24 hours. In man, similar application of triclosan resulted in only minimal percutaneous absorption (around 5%) following 24 hour occlusion to the skin. Subsequent metabolism occurs slowly ($T_{1/2}$ = 10 hours), followed by rapid urinary excretion, principally as the glucuronide.

5.3 Preclinical safety data

No preclinical findings relevant to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsifying wax (contains cetostearyl alcohol)
Carbomer 974P
Glycerol
Almond Oil, Refined
Terpineol
Perfume blend A2 (perfume 8399, perfume ES9078, perfume 2336A)
Potassium hydroxide solution 50% (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Collapsible aluminium tube with an internal lacquer coating.

Pack size - 30g.

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

Reckitt Benckiser Ireland Limited,
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 979/4/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd October 1978

Date of last renewal: 23rd October 2008

10 DATE OF REVISION OF THE TEXT

January 2009