Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dettol Med 4.8% w/w Concentrate for Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chloroxylenol 4.8mg in 100mg concentrate for Cutaneous solution

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Concentrate for cutaneous solution

Clear, amber liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Antiseptic cleansing of cuts, bites, abrasions and insect bites and stings.

4.2 Posology and method of administration

For cutaneous use

Dettol med should not be used undiluted

Cuts, bites, abrasions and insect stings - wash the area with 50 ml Dettol Med diluted to one litre (5%, 1:20) with water and cover with dry gauze or lint.
Once diluted the liquid becomes a milky white, opaque solution with pine odour.
Dettol med should not be used undiluted

Paediatric Patients
Not to be used on children under 12 months.

4.3 Contraindications

Known hypersensitivity to the active substance or any of the excipients

Eczematous conditions.

Not to be used on children under 12 months of age.

4.4 Special warnings and precautions for use

For external use only.

This product is only suitable for wound cleansing as a first aid measure and is not suitable for surgical antisepsis or use in a hospital setting.

Following accidental ingestion it is advised to consider dilution with milk or water if vomiting has not occured. If skin

or eye contamination has occured, copious irrigation should be performed. This should be followed by a careful eye examination for corneal burns. If corneal burns are noted, opthalmologic consultation should be obtained.

Do not use in or around the eyes, ears, nose or mouth.

4.5 Interaction with other medicinal products and other forms of interaction

No specific drug interaction studies have been undertaken; therefore the use of Dettol Med with any other topical products is not recommended.

4.6 Fertility, pregnancy and lactation

Dettol Med Cutaneous Solution 4.8 %w/w can be used during pregnancy under medical supervision.

It is not advised to apply Dettol Med Cutaneous Solution 4.8 %w/w to the skin of the breast during lactation.

4.7 Effects on ability to drive and use machines

Dettol Med has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse drug reactions are very rare (<1/10,000) following the topical use of Dettol Med.

The following outlines the skin and subcutaneous tissue disorders linked with the use of Dettol Med.

Skin and Subcutaneous Tissue Disorders	Very rare	Skin dystrophy, application site fissure, acrodermatitis, eczema, contact dermatitis, skin irritation, skin burning sensation, alopecia, papular rash, pruritus, erythema, skin discoloration, and skin exfoliation

4.9 Overdose

Overdose is unlikely when used as directed since the Dettol Med will run off the skin surface if an excessive amount is applied.
Chloroxylenol has a low systemic toxicity, when used as instructed.

There have been isolated reports of poisoning. Symptoms reported after oral ingestion include corrosion of the oral mucosa, larynx, and the gastrointestinal tract, bradycardia, hypotension, and renal failure. Large amounts may cause CNS depression. Pulmonary aspiration of chloroxylenol-based disinfectants may result in pneumonia, acute respiratory distress syndrome, and cardiorespiratory arrest.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptic.

ATC code: D08AE05

Chloroxylenol is a substituted phenol which has been widely used for many years as an ingredient of antiseptic/disinfectant products intended for external use. It is known to be bacteriocidal in low concentration to a wide range of Gram-positive and Gram-negative bacteria.

5.2 Pharmacokinetic properties

PCMX is well absorbed after oral dosing and almost totally excreted in the urine within 24 hours. PCMX has a t_{max} of ~30 to 60 minutes and a half life ~50 to 60 minutes. The clearance of PCMX is ~6 hours with no PCMX being detected in tissue after 24 hours. PCMX is metabolised in the liver and excreted in a conjugated form as a mixture of glucuronide and sulfate conjugates in a ratio of 6:1 with very low levels of free PCMX.

5.3 Preclinical safety data

Preclinical studies with Chloroxylenol, although limited, do not indicate a risk of genotoxicity, carcinogenicity or teratogenicity. Effects observed upon oral administration of a single dose of an undiluted formulation similar to Dettol Med included sedation, salivation and respiratory depression. Oral LD_{50} values varied between 9.7 and 17.4 ml/kg.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pine oil,
Isopropyl alcohol,
Castor oil soap,
Caramel (E150(c)),
Purified water

6.2 Incompatibilities

This product should not be mixed with any other medicinal product.

6.3 Shelf life

Two years
Once diluted the solution should be used immediately

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

White high density polythylene or white polypropylene orunpigmented polypropylene bottles with polypropylene screw cap.

Pack sizes: 125, 250, 500, 750, 1000 & 1250ml
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare Ireland Limited
7 Riverwalk
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8 MARKETING AUTHORISATION NUMBER

PA 979/4/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 October 2009
Date of last renewal: 22nd April 2014

10 DATE OF REVISION OF THE TEXT

February 2015