Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dettol Antiseptic Disinfectant 4.8% w/v, concentrate for cutaneous solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Chloroxylenol 4.8% w/v

Excipient(s) with known effect:

Pine Oil (contains fragrance with d-Limonene and Benzyl Alcohol)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Concentrate for cutaneous solution.
An amber coloured liquid with an odour of pine oil.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antiseptic for prophylaxis of topical infection in intact and abraded skin and for skin preparation prior to surgical or diagnostic procedures.

4.2 Posology and method of administration

Posology:

Adults:
Wash the affected area with product at 5% dilution (50 ml product in 1 litre of water)

Paediatric population:
Children over the age of 1 year: As above for adults
Children under the age of 1 year: Not for use in children under 1 year of age.

Method of administration:
Apply topically to relevant area as required.
Do not use undiluted.

4.3 Contraindications

Hypersensitivity to chloroxylenol or any of the excipients listed in section 6.1.

Do not use on eczematous conditions.
Not for use on children under 1 year of age.

4.4 Special warnings and precautions for use

If the condition persists or is aggravated, discontinue use and consult the doctor.
For external use only. Do not use undiluted.

Not for use around eyes, ears, nose or mouth. If contact is made, wash

thoroughly with cold water.
Not for use on large areas of the body or on sensitive skin.

If swallowed, wash out mouth and drink plenty of water or milk. If contact is made with eyes, wash thoroughly with cold water. In both cases consult your doctor.

Keep out of the sight and reach of children.

This medicine contains trace amounts of Benzyl Alcohol.
Benzyl Alcohol may cause allergic reactions and mild local irritation.

This medicine contains fragrance with d-Limonene.
D-Limonene may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interactions

Not applicable.

4.6 Fertility, pregnancy and lactation

Pregnancy:
No effects during pregnancy are anticipated, since systemic exposure from topical chloroxylenol use is negligible. As with all medicines, this product should be used with caution during pregnancy.

Breast-feeding:
It is unknown whether chloroxylenol or its metabolites are excreted in human milk. A risk to newborns/infants cannot be excluded. Application of the product to the breast is not recommended during breast-feeding.

Fertility:
No data on human fertility are available.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Adverse events which have been associated with chloroxylenol are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very Common ((≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (<1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

Contains castor oil, may cause skin reactions.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity
Skin and Subcutaneous Tissue Disorders	Not known	Skin sensitization, dermatitis contact[1], skin discolouration, rash
Administration Site Conditions	Not known	Application site irritation, application site burn

Description of Selected Adverse Reactions
[1] Contact dermatitis can be associated with pruritus, erythema, skin scaling, itching and stinging

Reporting of Suspected Adverse Reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

Symptoms:
Topical application of undiluted chloroxylenol can cause skin burning.

Oral ingestion may result in pharyngeal erosion, laryngeal oedema,stomatitis,bradycardia, hypotension, renal failure and CNS depression. Pulmonary aspiration following ingestion may result in pheumonia, acute respiratory distress syndrome and cardiorespiratory arrest. There have been reports of deaths by excessive consumption.

Management:
In the case of accidental ingestion or excess exposure, wash out mouth and drink plenty of water or milk and contact your doctor immediately. Careful observation of airway patency for 24-48 hours should be made post-ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D08AE05, Phenol and derivatives
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 bactericidal in low concentration to a wide range of Gram positive and Gram negative bacteria.

5.2 Pharmacokinetic properties

Chloroxylenol is well-absorbed when applied to the skin. It is extensively metabolised in the body, probably by the liver, and rapidly excreted, mainly in the urine, as sulphate and glucuronide conjugates. Chloroxylenol has a low systemic toxicity, even at dosage levels many times higher than those likely to be absorbed during normal usage of Dettol Liquid.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pine oil (contains fragrance with d-Limonene and Benzyl Alcohol),
Isopropyl alcohol,
Castor oil soap
Caramel
Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

No special requirements.

6.5 Nature and contents of container

Polypropylene and polyvinylchloride bottles with polypropylene screw cap with PVdC wad.

Pack sizes:125 ml, 250 ml, 275 ml, 500 ml, 550 ml, 750 ml

4L HDPE bottles with polypropylene screw cap

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

For external use only.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/004/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983
Date of last renewal: 1st April 2008

10 DATE OF REVISION OF THE TEXT

March 2021