

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dettol Liquid

Dettol Antiseptic Disinfectant 4.8% w/v Concentrate for Cutaneous Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredient</u>	<u>% w/v</u>	<u>Specification</u>
Chloroxylenol	4.8	BP

3. PHARMACEUTICAL FORM

Concentrate for cutaneous solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Medical - for cuts, bites, abrasions and insect stings.

Personal hygiene - for douching, dandruff; and spots and pimples.

4.2. Posology and Method of Administration

For external use only.

(a) Medical uses

For cuts, bites, abrasions and insect stings: wash the area with one tablespoonful of Dettol diluted in a half pint of water and cover with dry gauze or lint.

For urgent application, Dettol may be used undiluted, but not on sensitive skins.

(b) Personal hygiene

For douching (when medically advised): two teaspoonfuls of Dettol diluted in two pints of warm water.

For dandruff: one tablespoonful of Dettol diluted in one pint of warm water. Saturate hair and scalp for 10 minutes, then shampoo.

For spots and pimples: bathe the affected area daily with one tablespoonful of Dettol diluted in half a pint of warm water (not for eczematous conditions).

4.3. Contra-Indications

Not applicable.

4.4. Special Warnings and Special Precautions for Use

For external use only.

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 reach of children.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

Not applicable.

4.6. Pregnancy and Lactation

Not applicable.

4.7. Effects on Ability to Drive and Use Machines

Not applicable.

4.8. Undesirable Effects

Not applicable.

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

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. Pre-clinical Safety Data

No preclinical findings of relevance have been reported.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Pine oil,

Isopropyl alcohol,
Castor oil,
Caustic soda solution,
Caramel
Water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf-Life

Three years.

6.4. Special Precautions for Storage

There are no special precautions for storage.

6.5 Nature and contents of container

Polypropylene and Polyvinylchloride bottles with **polypropylene** screw cap with **PVdC** faced wadding.

Pack sizes: 125, 250, 500, 750, 1000ml.

Plastic Bottles

Pack Sizes: 2L, 4L and 5L.

6.6. Instruction for Use, Handling and Disposal

For external use only.

7. MARKETING AUTHORISATION HOLDER

Reckitt Benckiser (UK) Limited
103-105 Bath Road

Slough, SL1 3UH
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

PL 19718/0008

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

4th November 2002

10 DATE OF REVISION OF THE TEXT

22/11/2010