APPLICANT	**:Reckitt Benckiser Pharmaceuticals (Pty) Ltd**	**Submitted: October 2023**
PROPRIETARY NAME (DOSAGE FORM)	**:Dettol Antiseptic Liquid**	**MODULE 1**
STRENGTH	**:4.8 g Chloroxylenol per 100 ml**	**1.5.5**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

DETTOL ANTISEPTIC LIQUID

Chloroxylenol 4,8 g per 100 ml

Read all of this leaflet carefully because it contains important information for you

DETTOL ANTISEPTIC LIQUID is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use DETTOL ANTISEPTIC LIQUID carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet:

1. What DETTOL ANTISEPTIC LIQUID is and what it is used for

2. What you need to know before you use DETTOL ANTISEPTIC LIQUID

3. How to use DETTOL ANTISEPTIC LIQUID

4. Possible side effects

5. How to store DETTOL ANTISEPTIC LIQUID

6. Contents of the pack and other information

1. WHAT IS DETTOL ANTISEPTIC LIQUID AND WHAT IT IS USED FOR:

DETTOL ANTISEPTIC LIQUID IS FOR EXTERNAL USE ONLY. DO NOT SWALLOW.

DETTOL ANTISEPTIC LIQUID is a concentrated antiseptic solution proven to be effective against a range of harmful micro-organisms including bacteria *E.coli, Salmonella, Listeria*, MRSA, *E Hirae, Vibrio cholera*; fungi and viruses H1N1, H5N1, Influenza A2, corona virus 229E, SARS-CoV-2 (COVID-19 Virus).

It can be used for antiseptic cleansing of wounds, cuts, grazes and insect bites.

It can be used for surfaces disinfection of floors and hard surfaces.

DETTOL ANTISEPTIC LIQUID is not recommended as a hand sanitiser for the Covid-19 virus.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DETTOL ANTISEPTIC LIQUID:

Do not use:

DO NOT SWALLOW. FOR EXTERNAL USE ONLY.

DETTOL ANTISEPTIC LIQUID if you have eczema, a skin condition or are allergic to any of the ingredients.

Undiluted DETTOL ANTISEPTIC LIQUID.

DETTOL ANTISEPTIC LIQUID repeatedly.

DETTOL ANTISEPTIC LIQUID in children under 1 year of age.

DETTOL ANTISEPTIC LIQUID near your eyes, ears, nose or mouth.

Warnings and precautions:

Special care when using DETTOL ANTISEPTIC LIQUID:

If contact is made with eyes, wash them thoroughly with cold water.

If swallowed, wash out mouth and drink plenty of water or milk.

If inhaled move to fresh air.

Wear gloves and eye protection when performing surface disinfection cleaning.

In both cases seek medical advice immediately and take this bottle with you.

Other medicines and DETTOL ANTISEPTIC LIQUID:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

There are no known drug interactions with topical chloroxylenol.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using DETTOL ANTISEPTIC LIQUID.

Do not apply DETTOL ANTISEPTIC LIQUID to your breasts when breastfeeding your baby.

Driving and using machines

Chloroxylenol has no or negligible influence on the ability to drive or use machinery.

3. HOW TO USE DETTOL ANTISEPTIC LIQUID:

FOR EXTERNAL USE ONLY. Always dilute the product before use.

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

DIRECTION FOR ANTISEPTIC USE: For wounds, cuts, abrasions and insect bites: wash the affected area with 3 medicine measures of Dettol Antiseptic Liquid (15 ml) diluted in a glass of water (300 ml). (one medicine measure = 5 ml).

DILUTION FOR SURFACE USE: Floors and hard surface disinfection: dilute 20 ml in 100 ml of water. Apply to surface and leave on for 3 minutes. Remove by wiping the surface.

4. POSSIBLE SIDE-EFFECTS:

DETTOL ANTISEPTIC LIQUID can have side-effects.

Not all side-effects reported for DETTOL ANTISEPTIC LIQUID are included in this leaflet.

Should your general health worsen whilst using DETTOL ANTISEPTIC LIQUID or if you experience any untoward effects whilst using DETTOL ANTISEPTIC LIQUID, please consult your health care provider for advice.

If any of the following side effects occur, speak to your doctor immediately:

May cause local skin reactions eg. contact dermatitis with itching, redness, stinging, skin scaling and depigmentation.

Accidental ingestion may cause vomiting, diarrhoea, respiratory distress and cardiovascular collapse. Seek medical advice immediately or go to emergency department of hospital or contact a poison control centre.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DETTOL ANTISEPTIC LIQUID.

5. HOW TO STORE DETTOL ANTISEPTIC LIQUID:

Store all medicines out of reach of children.

Store at or below 25 °C.

Store away from food stuffs.

Keep in the original container, tightly closed and upright when not in use

Do not use the product after the expiry date shown on the bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What DETTOL ANTISEPTIC LIQUID contains:

The active substance is Chloroxylenol 4,8 g in 100 ml.

The other ingredients are pine oil, caramel, isopropyl alcohol, castor oil soap and water.

What DETTOL ANTISEPTIC LIQUID looks like and contents of the pack:

DETTOL ANTISEPTIC LIQUID is a clear amber liquid with pine oil odour free from particulate matter. The liquid is packed in either 50 ml, 125 ml, 500 ml, 750 ml or 1 litre in clear plastic bottles.

REGISTRATION NUMBER:

G/13.1/2345

Holder of the certificate of registration:

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein, 1601

+2711 871 1611

This leaflet was last revised in:

Date on the registration certificate: 20 April 1983

Date of the revised patient information leaflet: 22 January 2024

Registration number:

G/13.1/2345

Access to the corresponding Professional Information:

Available electronically at https://cpdcentre.co.za/rb-product-inserts/

NRCS Registration: NRCS/8054/294116/1240