Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Liquid Paraffin BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paraffin, liquid, 100% v/v.

3 PHARMACEUTICAL FORM

Oral liquid
Transparent, colourless, oily liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Liquid Paraffin is an intestinal lubricant. It is indicated for the treatment of occasional constipation.

4.2 Posology and method of administration

Route of administration: Oral.
Recommended Dosage:
Adults: 1 - 4 tablespoonfuls daily.
Children: Not recommended.

4.3 Contraindications

Hypersensitivity to liquid paraffin.
Neurological conditions or disorders of swallowing that could predispose to aspiration of liquid paraffin (see 4.8 *Undesirable effects*).

4.4 Special warnings and precautions for use

If symptoms persist, or if undesirable effects occur, consult your doctor.
The product is for occasional use only. Prolonged use is not recommended.
Not for use in children.

4.5 Interaction with other medicinal products and other forms of interaction

Inappropriate or prolonged use may decrease the absorption of nutrients, including the fat soluble vitamins A, K, E and D.

4.6 Pregnancy and lactation

Safety in pregnancy has not been established.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Leakage of oil past the anal sphincter can occur, resulting in anal seepage and irritation.
Liquid paraffin is absorbed to a slight extent. There have been reports suggesting an association between the occurrence of foreign-body granulomata in the abdominal viscera and the prolonged intake of liquid paraffin from dietary and other sources. Although these changes do not appear to be clinically significant, it is recommended that prolonged use of Liquid Paraffin should be avoided.
Lipoid pneumonia has been reported following the aspiration of liquid paraffin.
Inappropriate or prolonged use of liquid paraffin may decrease the absorption of nutrients, including the fat-soluble vitamins A, K, E and D.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Liquid Paraffin is an intestinal lubricant.

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

Liquid Paraffin has been widely used for many years.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Amber glass bottles with a polyethylene closure with a LDPE liner.
Pack size: 100 ml, 200 ml, 500 ml

High density polyethylene container with pilfer proof wadded cap.
Pack size: 4.55 litres

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

Ricesteele Manufacturing Limited
Cookstown Industrial Estate
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8 MARKETING AUTHORISATION NUMBER

PA 95/20/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 10 November 2003

10 DATE OF REVISION OF THE TEXT

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