

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Liquid Paraffin BP 100% v/v Oral Liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains Liquid Paraffin 100% v/v.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral liquid

A colourless, transparent, oily liquid, free from fluorescence in daylight.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Used for the temporary relief of constipation.

4.2 Posology and method of administration

Recommended dosage:

Adults: 10-30 ml as required.

Elderly: Not recommended for bedridden elderly patients since they are more prone to aspiration of oil droplets, which may produce lipid pneumonia.

Children: Not recommended for children under 6 years of age, unless prescribed by a doctor.

Infants and neonates: Not recommended

Special groups: Patients under medical care should not take liquid paraffin, unless recommended by their doctor.

4.3 Contraindications

Liquid paraffin should not be used in patients with appendicitis, undiagnosed rectal bleeding, congestive heart failure, intestinal obstruction, dysphagia.

4.4 Special warnings and precautions for use

Avoid prolonged use.

If symptoms persist consult your doctor.

Habitual use must be avoided. Overuse or extended use may cause dependence for bowel function.

4.5 Interaction with other medicinal products and other forms of interaction

Potassium sparing diuretics or potassium supplements: Chronic use or overuse of laxative may reduce serum potassium concentrations by promoting excessive potassium loss from the intestinal tract, thus interfering with potassium-retaining effects of diuretics.

Anticoagulants, oral contraceptives, digitalis glycosides, fat soluble vitamins: concurrent use of liquid paraffin may interfere with the proper absorption of these or other medications and reduce their effectiveness.

4.6 Pregnancy and lactation

Repeated use of liquid paraffin may decrease absorption of foods, fat soluble vitamins and some oral medications. Hypoprothrombinaemia and haemorrhagic disease of the neonate have occurred following chronic use during pregnancy.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Anal seepage of paraffin and consequent anal irritation can occur after prolonged use.

Granulomatous reactions caused by absorption of small quantities of liquid paraffin.

Lipoid pneumonia (by accidental inhalation) may occur and therefore caution is required in patients with swallowing difficulties.

4.9 Overdose

No information provided.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Liquid paraffin has lubricant properties suited to use in the alimentary system to relieve constipation.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

None known.

6.3 Shelf Life

18 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

100ml, 150ml and 500ml in amber glass bottles.

500ml, 2 litres and 5 litres in high density polyethylene bottles.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Ltd.

Ballymacarbry

Clonmel

Co. Tipperary

Trading as:

Pinewood Healthcare

Co. Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 281/52/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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August 2005