

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Liquid Paraffin

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Liquid Paraffin 100% v/v.

3. PHARMACEUTICAL FORM

Liquid.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the temporary relief of constipation.

4.2. Posology and Method of Administration

Oral

Recommended doses and dosage schedules:

Adults including the elderly: 10-30ml when required.

Children over 3 years: 5-20ml when required.

Children under 3 years: not recommended.

4.3. Contra-Indications

Use is contraindicated in children under 3 years of age.

4.4. Special Warnings and Special Precautions For Use

Avoid prolonged use.

Consult your doctor if laxatives are needed every day, if you have persistent abdominal pain or have a condition which makes swallowing difficult.

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

There may be interference with the absorption of fat soluble vitamins.

4.6. Pregnancy and Lactation

As with all medicines avoid during early pregnancy and lactation.

4.7. Effects on Ability to Drive and Use Machines

None.

4.8. Undesirable effects

Anal seepage of paraffin with consequent anal irritation after prolonged use. Granulomatous reaction caused by absorption of small quantities of liquid paraffin. Lipoid pneumonia (by accidental inhalation) may occur, therefore caution is required in patients with swallowing difficulty.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9. Overdose

If large doses are ingested withdraw medication. Supportive treatment may be required.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Liquid paraffin acts as a lubricant and penetrates and softens the stools.

5.2. Pharmacokinetic Properties

Liquid paraffin is indigestible and is absorbed only to a limited extent following ingestion.

5.3. Pre-clinical Safety Data

None.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

None.

6.2. Incompatibilities

None.

6.3 Shelf life

36 months unopened.

6.4. Special Precautions for Storage

Store below 25°C. Protect from light.

6.5 Nature and contents of container

150ml: Amber glass bottle with plastic cap.

6.6. Instructions for Use, Handling and Disposal

None.

7 MARKETING AUTHORISATION HOLDER

L. C. M. Ltd.
Linthwaite Laboratories
Huddersfield
HD7 5QH.

8. MARKETING AUTHORISATION NUMBER(S)

PL 12965/0022

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

20 August 1993 / 22 October 1998

10 DATE OF REVISION OF THE TEXT

13/04/2015