

## **1. NAME OF THE MEDICINAL PRODUCT**

Galways Pure Liquid Paraffin

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Contains:

Liquid Paraffin 200ml

## **3. Pharmaceutical form**

Liquid

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Galway's Pure Liquid Paraffin is indicated for the following:

#### **Internal**

- Symptomatic treatment of constipation given orally or as enema.

#### **External**

- Emollient to the skin.
- Removal of crusts.
- Cleanser for dry and inflamed skin.

### **4.2 Posology and method of administration**

#### **Posology**

#### **Internal**

Adults and children 12 years and above: 15ml 2 times daily or 15ml in the evening

Children 3 years and above: 5ml to 10ml 2 times daily or 10ml in the evening.

Children below 3 years: Not recommended for use.

#### **External**

Apply to the affected area.

#### **Method of administration**

The product can be taken orally and applied topically.

### **4.3 Contraindications**

Liquid paraffin is contra-indicated in:

- Patients suffering from abdominal pains or intestinal blockage.
- Children under the age of 3 years.
- Patients suffering from abdominal pain, nausea or vomiting
- Patients having difficulties in swallowing (due to the risk of bronchial inhalation and lipid pneumonia).
- Patients with impaired neurodevelopment.
- During pregnancy and breastfeeding

### **4.4 Special warnings and precautions for use**

It should not be taken immediately before going to bed.

Do not take with meals as it may delay digestion.

Avoid Prolonged use.

Excessive oral or rectal dosage with liquid paraffin may result in anal seepage and irritation, excessive purgation and watery diarrhoea.

Liquid paraffin is absorbed to a slight extent and may give rise to foreign body granulomatous reactions.

Lipoid pneumonia has been reported after aspiration of liquid paraffin. Because of the risk of aspiration, oral liquid paraffin should not be given to patients who have difficulty swallowing or to those with impaired neurodevelopment.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Tell your doctor about all the medicines you take including prescription and nonprescription medications, vitamins, and herbal supplements. Especially tell your doctor if you take vitamins. This product may interfere with the absorption of fat soluble vitamins.

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy and Breastfeeding

No reliable data exists concerning the possibility of teratogenesis in humans, Liquid paraffin is not absorbed by the body; however it does interfere with resorption of fat soluble vitamins (A, D, E, K), which may have negative health impact on newborns (in the form of nose bleeds). Consequently, the use of this product during pregnancy is not recommended.

#### **4.7 Effects on ability to drive and use machines**

Not relevant

#### **4.8 Undesirable effects**

Liquid paraffin is well tolerated when administered at the recommended dosage. Excessive oral or rectal dosage with liquid paraffin may result in anal seepage and irritation, excessive purgation and watery diarrhoea.

#### **4.9 Overdose**

##### Symptoms

Chronic ingestion of liquid paraffin may rarely be associated with impaired absorption of fat soluble vitamins and possibly other compounds. Prolonged use should be avoided.

##### Management

In acute overdosage with liquid paraffin, treatment is symptomatic and supportive.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Lubricant laxative, Emollient

ATC code: A06AA01

Taken orally, Liquid Paraffin acts as a lubricant which penetrates and softens the stools. Therefore it is used in the symptomatic treatment of constipation and in painful conditions of the anus and rectum such as haemorrhoids and anal fissure. It has also been given as an enema in a usual dose of 120ml.

Externally, liquid paraffin may be used as an ingredient of ointment bases, as an emollient and cleanser in certain skin conditions and as an ophthalmic lubricant in the management of dry eyes.

#### **5.2 Pharmacokinetic properties**

The pharmacokinetics of liquid paraffin shows that liquid paraffin is indigestible and is absorbed only to a limited extent following oral administration.

#### **5.3 Preclinical safety data**

No further data.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Liquid Paraffin

#### **6.2 Incompatibilities**

Not applicable.

#### **6.3 Shelf Life**

3 years

**6.4 Special precautions for storage**

Store below 30°C.

**6.5 Nature and contents of container**

200ml Amber bottle with aluminium screw cap.

**6.6 Special precautions for disposal and other handling**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7. APPLICANT/MANUFACTURER**

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