

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Linodfluid®.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Bornyl acetate 0.29 % w/w, alpha-pinene 0.47 %w/w and arnica liquid extract 0.50mg (isopropyl alcohol 50% (1;20))

## 3 PHARMACEUTICAL FORM

Cutaneous solution

Clear pale green liquid with aromatic odour

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the symptomatic relief of muscular pain and stiffness including backache, lumbago, fibrositis, cramp and bruising.

### 4.2 Posology and method of administration

#### Posology

Apply sparingly to the affected part four times a day. Lightly massage if necessary.

#### *Paediatric population*

Children under 6 years: Not to be used.

#### Method of administration

For external use only.

### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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

- Not to be used on broken skin.
- Avoid contact with eyes and mucous membranes.
- If conditions worsen or persist, seek medical advice.
- If pregnant or lactating, consult a physician before using.

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

None known

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

##### Pregnancy

There is no evidence of the safety of Lindofluid® in pregnancy but it has been widely used for many years and no adverse events have been reported.

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

Not relevant.

#### **4.8 Undesirable effects**

Irritant skin reactions may occur in the presence of turpentine oil.

##### **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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

Isopropyl alcohol is approximately twice as toxic as ethanol. A dose of about 250ml pure isopropyl alcohol has been reported to be fatal in adults.

In a single case of accidental oral ingestion, an adult swallowed 40 to 50ml Lindofluid®. The patient recovered fully without any treatment.

If accidental oral ingestion does occur, the patient should be kept warm. The stomach may be lavaged, but care should be taken to prevent pulmonary aspiration of the return flow. If significant respiratory distress is present, steps should be taken to protect the airway from aspiration and to provide ventilatory assistance if indicated.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Other topical products for joint & muscular pain

ATC code: M02AX

Bornyl acetate: is a rubefacient for use in muscle stiffness and rheumatism.

Alpha-pinene: is a rubefacient for use in muscle stiffness and rheumatism.

Arnica: stimulates the peripheral blood supply when externally applied and aids wound healing, particularly bruising, and muscle pain. It contains sesquiterpene lactones, such as helenalin, which have anti-inflammatory activity.

### **5.2 Pharmacokinetic properties**

#### Absorption

The active ingredients are effective after topical administration and are absorbed percutaneously.

#### Biotransformation

The main mechanisms of biotransformation of the terpenes,  $\alpha$ -pinene and bornyl acetate, are hydroxylation, acetylation reduction, molecular rearrangement and conjugation with glucuronic acid.

### **5.3 Preclinical safety data**

Bornyl acetate: The acute and chronic toxicity of bornyl acetate is very low.

$\alpha$ -pinene: The acute oral toxicity in rats is very low with LD<sub>50</sub> values variously reported as 1,400 to 5200mg/kg body weight and 2100 to 3700mg/kg body weight.

The chronic toxicity of  $\alpha$ -pinene is very low. Inflammatory eczema-like alterations and scab formation appeared after chronic application of  $\alpha$ -pinene on depilated rat

abdomen skin. This condition improved eight days after discontinuation of the application and normal hair growth re-occurred in this area.

Arnica: The toxicity after oral administration of arnica flowers is difficult to assess. In animal studies, toxic and lethal doses of orally administered doses of arnica flowers produced cardiac arrhythmias associated with dyspnea and reduction of tidal volume and fatal collapse. Similar reactions after topical administration have not been seen.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Aldehyde C12 laurin, aniseed aldehyde, camphor, lemon oil, coumarin, diisopropyl adipate, eucalyptus oil, melissa extract; spruce needle oil, isobornyl acetate, mountain pine oil, lavandin 30/32% abrial,  $\alpha$ -terpineol, menthol, rosemary oil, patina green II 5/DR 4089 (contains E104, E110, E124 and E103), isopropyl alcohol, purified water.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

Clear, PVC bottle fitted with a polyethylene insert and a polypropylene screw cap containing either 100ml or 250ml Lindofluid®.

Not all pack sizes may be marketed.

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

Avoid contact with eyes and mucous membranes. The lotion is flammable and should not be stored or used near sparks or naked flames, including lighted cigarettes. Do not incinerate.

## **7 MARKETING AUTHORISATION HOLDER**

Tillomed Laboratories Limited  
220 Butterfield  
Great Marlings  
Luton  
LU2 8DL  
UK

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 11311/0532

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 17/11/1999

Date of latest renewal: 22/08/2005

## **10 DATE OF REVISION OF THE TEXT**

04/02/2020

## **11 DOSIMETRY (IF APPLICABLE)**

**12 INSTRUCTIONS FOR PREPARATION OF  
RADIOPHARMACEUTICALS (IF APPLICABLE)**