

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ransom's Glycerin, Lemon, Honey & Ipecacuanha Linctus

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glycerol BP 0.25 ml/5 ml

Honey 0.5 g/5 ml

Citric Acid Monohydrate BP 25 mg/5 ml

Lemon Oil BP Terpeneless 0.0005 ml/5 ml

Syrup BP 3.75ml/5 ml

Ipecacuanha Liquid Extract 0.025 ml/5 ml

3 PHARMACEUTICAL FORM

Oral liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of coughs and sore throats.

4.2 Posology and method of administration

Adults, the elderly and children over 12 years of age

Two 5 ml spoonfuls to be taken 3 or 4 times daily.

Children aged 3 to 12 years

One 5 ml spoonful to be taken 3 or 4 times daily.

Children under 3 years

Not recommended.

4.3 Contraindications

This product is not recommended for use in diabetes mellitus because of the sugar content.

4.4 Special warnings and precautions for use

This product contains a small amount of ipecacuanha, which is potentially cardiotoxic, and should not be used in patients on antiarrhythmic therapy.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

As with many other medicines, this product should be avoided in the first three months of pregnancy and during lactation unless the benefits outweigh any risks. No significant problems have been reported in breast-fed infants from mothers taking the product.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Occasionally gastric irritation, nausea and vomiting may occur.

4.9 Overdose

Overdosage is unlikely (due to the ipecacuanha) as large doses are emetic but if it does occur there have been cases of cardiotoxicity.

Other symptoms may include dryness of the mouth, thirst, nausea, headache and vomiting.

If ingestion is recent then gastric lavage and the use of activated charcoal may be employed. Treatment consists of correction of fluids and electrolytes, ECG monitoring and general supportive therapy.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

At the levels at which it is present in the product each dose of 2 x 5 ml is equivalent to 0.950 - 1.050 mg of ipecacuanha alkaloids; At such a level these alkaloids offer an expectorant action which is probably due to a reflex action from irritation of the nasal mucous membrane.

The glycerol, honey and syrup act as demulcents and provide a soothing medium for an irritated throat.

The citric acid Monohydrate and the lemon oil, Terpeneless both add to the sharpness of the product and enhance the flavour.

5.2 Pharmacokinetic properties

Glycerol BP

It is readily absorbed from the intestine and metabolised to carbon dioxide and glycogen.

Honey, Citric Acid Monohydrate BP and Lemon Oil, Terpeneless BP

Little is reported in the literature on the Pharmacokinetic of these substances.

Syrup BP

Syrup BP is a 66.7% w/v solution of sucrose in water; Sucrose is hydrolysed by enzymes in the mouth and in the gastrointestinal tract to glucose and fructose.

Ipecacuanha Liquid Extract BP

The principal alkaloids in Ipecacuanha Tincture BP are emetine and cephaeline; little data are given in the literature about the Pharmacokinetic of the expectorant action of ipecacuanha or its related alkaloids but it is thought to cause a reflex action by irritation of the nasal mucous membrane.

5.3 Preclinical safety data

No relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96%)
Nipasept Sodium
Water, Potable

6.2 Incompatibilities

No major incompatibilities have been reported.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

The product should be protected from light; the product is supplied in amber glass bottles. Store below 25°C.

6.5 Nature and contents of container

Amber glass bottle with a plastic “J” cap or

Amber glass bottle with a roll-on aluminium cap with an expanded polythene liner.

Pack size: 100 ml and 200 ml.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Wise Pharmaceuticals Ltd
Hani Wells Business Park, Unit 7,
Hardicker Street,
Manchester,
M19 2RB
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 18374/0014

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/01/2004 / 14/07/2006

10 DATE OF REVISION OF THE TEXT

14/07/2006