

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ransom's Glycerin, Lemon & Honey Linctus or Morrisons Glycerin Lemon & Honey Linctus

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Glycerol 5.0% v/v
Honey 10.0% w/v
Citric Acid Monohydrate 0.5% w/v
Lemon Oil Terpeneless 0.01% v/v
Syrup 75.0% v/v

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Oral solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The symptomatic treatment of coughs and sore throats.

4.2 Posology and method of administration

For oral administration

Adults and the elderly

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

Children over 1 year

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

Not recommended for infants under 1 year.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Patients with rare hereditary problems or fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Not recommended for infants under 1 year.

4.4 Special warnings and precautions for use

This product is not suitable for use by diabetics.

If symptoms persist, consult your doctor.

4.5 Interactions 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

None anticipated at the recommended dosage.

4.9 Overdose

Overdosage is unlikely but if it does occur then treatment consists of general supportive therapy and may include gastric lavage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: R05X Other Cold Combination Preparations

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 B.P.

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

Honey, Citric Acid Monohydrate B.P. and Lemon Oil, Terpeneless B.P.

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

Syrup B.P.

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

5.3 Preclinical safety data

No relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96%)

Nipasept Sodium (a mixture of the sodium salts of methyl-, ethyl- and propyl-4-hydroxybenzoate)

Water, potable

6.2 Incompatibilities

No major incompatibilities have been reported.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Amber glass bottle with a plastic “J” cap or

Amber glass bottle with a metal roll-on pilfer proof closure (ROPP) with plastic liner in a carton . Plastic dosage cup supplied.

Pack size: 100 ml and 200 ml.

Not all pack sizes may be marketed.

6.6 Instructions for use/handling

None.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 18374/0013

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF
AUTHORISATION**

9th March 2005

10 DATE OF REVISION OF THE TEXT

09/03/2005