1. NAME OF THE MEDICINAL PRODUCT

Avrolin Cough Linctus

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	per 5ml
Ipecacuanha Liquid Extract	0.015ml
Purified Honey	0.75ml
Glycerol	1.11g
Citric Acid	50mg
Lemon Oil	0.6µl
Lime Oil	1.25µl

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Linctus

4. Clinical particulars

4.1 Therapeutic indications

Avrolin Cough Linctus helps to naturally relief throat irritations associated dry and stubborn coughs. It is also useful for the relief of bronchial congestion.

4.2 Posology and method ofadministration

Method of administration
For oral administration.

Posology
Adults and children over 12 years: 15ml

Children:

2 to 5 years: 5ml

6-12 years: 10ml

Not suitable for children under 1 year.

The dose may be taken up to 2 to 3 times daily, if needed.

Elderly: There is no need for dosage reduction in the elderly.

4.3 Contraindications

- Hypersensitivity or intolerance to any of the ingredients.
- Infants under 1 year because of the risk of causing infant botulism
- Pregnancy and breast feeding.
- Patients in shock or those at risk from seizures
- Patients with cardiovascular disorders

4.4 Special warnings and precautions for use

If symptoms persist consult your doctor.

Keep all medicines out of the reach of children.

Ipecacuanha should not be given to patients in shock or those at risk from seizures.
Patients with cardiovascular disorders are at risk if ipecacuanha is absorbed.

4.5 Interaction with other medicinal products and other forms of interaction

Action of Ipecacuanha may be delayed or diminished if it is given with or after charcoal; antiemetics may also diminish its effect.

Intestinal absorption of aluminium ions may be enhanced by oral administration of citrates.

4.6 Pregnancy and Lactation

The safety of Ipecacuanha, Glycerin, Honey, Lemon and Lime Linctus during pregnancy and lactation has not been established, however, as with all medicines use should be avoided during pregnancy unless recommended by a doctor.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Immune system disorder: hypersensitivity reactions, including anaphylaxis.

Large doses may produce an irritant effect on the gastric mucosa causing nausea, vomiting and diarrhoea.

4.9 Overdose

Overdose with this preparation is unlikely to occur due to the low concentrations of the ingredients, however, in the event of acute overdosage, activated charcoal should be given to delay absorption followed if necessary by gastric lavage. Further treatment should be symptomatic and along supportive lines.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ipecacuanha has expectorant action in productive cough in doses of up to about 1.4mg of total alkaloids.

Citric acid is mildly expectorant and has been used in preparations for the treatment of coughs.

Glycerin and honey have demulcent properties and will soothe irritated sore throats and possibly block sensory cough receptors within the respiratory tract.

Lemon and lime are used as a carminative and flavour. They have been used with other agents in preparations for the relief of congestive respiratory-tract disorders.

5.2 Pharmacokinetic properties

Purified Honey:
Honey is absorbed from the gastrointestinal tract.

Glycerol:
Glycerol is readily absorbed from the gastrointestinal tract and undergoes extensive metabolism, principally in the liver; it may be used in the synthesis of lipids, metabolised to glucose or glycogen, or oxidised to carbon dioxide and water. It may also be excreted in the urine unchanged.

Lemon Oil & Lime Oil:
The structurally related terpinoids citral, citronellol, geranyl acetate, linalool and linalyl acetate present in most essential oils are rapidly absorbed in the body. Citronellol, geraniol and citral follow the same metabolic pathway, undergoing oxidation to carboxylic acids. Some is then decarboxylated and the remaining portion is oxidised to yield 2,6-dimethyl-2,6-octadienedioic acid from citral and geraniol or the dihydro form of the acid from citronellol. Some of the acid from citral or geraniol may be further reduced to

the dihydro acid. At low doses decarboxylation is the major metabolic route; at high doses, some terpinoids may be excreted unchanged.
Excretion is rapid with little enterohepatic circulation. Linalol is readily conjugated to its glucuronide. Their excretion takes place through the lungs, skin and kidneys.

5.3 Preclinical safety data
Not Applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium Benzoate
Xanthan Gum
Sorbitol Solution
Polysorbate 80
Caramel
Lemon Flavour
Deionised water

6.2 Incompatibilities
None stated.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store below 30°C. Protect from light.

6.5 Nature and contents of container
Amber bottle with Ropp aluminium screw cap, fitted with an inner plastic measuring cap.
Pack size 100 ml.

6.6 Special precautions for disposal
No special requirements.

7 . APPLICANT/MANUFACTURER

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