

1. NAME OF THE MEDICINAL PRODUCT

Cofex Lozenges

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lozenge contains:

Ammonium Chloride1mg

Ipecacuanha Liquid Extract2.5µl

Liquorice Extract50mg

Peppermint Oil1µl

Aniseed Oil1µl

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cofex Lozenges is presented as a round, faint brown Lozenge.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cofex Lozenges is a non-drowsy preparation for the relief of coughs, bronchial & nasal congestions and catarrh.

4.2 Posology and method of administration

Adults and children 12 years and above

2 Lozenges to be sucked slowly 3 to 4 times a day

Children

1-5 years: 1 Lozenge to be sucked slowly 3 times a day

6-12 years: 2 Lozenges to be sucked slowly 3 times a day.

Method of administration

For oral administration.

4.3 Contraindications

This product is contraindicated in individuals with known hypersensitivity to any of the components of the preparation listed in section 6.1.

Cofex Lozenges is also contra-indicated in patients with narrow-angle glaucoma or benign prostatic hypertrophy and patients with hepatic or renal impairment. It is also contra-indicated in patients with cardiovascular disorders and in those at risk of seizures.

4.4 Special warnings and precautions for use

Avoid taking on an empty stomach. Cofex Lozenges when taken with food is well tolerated.

The product should be used with caution in pregnancy and during breast feeding.

4.5 Interaction with other medicinal products and other forms of interaction

The action of ipecacuanha may be delayed or diminished if it is given with or after charcoal. Antiemetics may also diminish its effects.

Adverse effects may be more likely if peppermint oil is taken with alcohol.

There is some evidence that peppermint oil can inhibit the cytochrome P450 isoenzyme CYP3A4 and may affect the clearance of drugs whose metabolism is mediated by this enzyme.

4.6 Fertility, pregnancy and lactation

The product should be used with caution in pregnancy and lactation

Pregnancy

Heavy consumption of liquorice during pregnancy has been associated with an increased risk of preterm delivery in a study conducted in Finnish women.

4.7 Effects on ability to drive and use machines

No additional information.

4.8 Undesirable effects

Side effects are rare and usually mild and may be reduced by giving the drug with meals. Large doses have an irritant effect on the gastrointestinal tract and are reported to cause gastrointestinal disturbances like nausea, vomiting and diarrhoea.

Large doses of Ammonium Chloride may cause profound acidosis and hypokalemia. Hepatic encephalopathy due to the inability of the liver to convert increased load of ammonium ions to urea has also been reported from excessive doses.

The absorption of emetine which is most likely if vomiting does not occur after overdose of ipecacuanha, may give rise to adverse effects on the heart, such as conduction abnormalities or myocardial infarction. These combined with dehydration due to vomiting may cause vasomotor collapse followed by death.

Excessive ingestion of liquorice has been reported to cause hypokalaemia, hypertension, congestive heart failure, arrhythmias, fatal cardiac arrest, headache, muscle weakness, myopathy, myoglobinuria, paralysis, hyperprolactinaemia and amenorrhoea. The effects are thought to be due to inhibition of 11- β -hydroxysteroid dehydrogenase (cortisol oxidase) by glycyrrhetic acid (a metabolite produced by the hydrolysis of glycyrrhizic acid) resulting in increased concentrations of cortisol in the body.

4.9 Overdose

In large doses, Ammonium Chloride may produce nausea and vomiting. Profound acidosis and hypokalemia may also occur.

Persistent bloody vomiting and bloody diarrhoea and mucosal erosions of the entire GIT has been reported following large doses of ipecacuanha.

Excessive mineralocorticoid effects manifesting as sodium and water retention and hypokalaemia have been reported following excessive ingestion of liquorice.

Management:

After 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

Ammonium Chloride:

Ammonium Chloride is an ammonium salt, which possesses expectorant properties useful in the treatment of productive cough.

Expectorants are considered to increase the volume of secretions in the respiratory tract thereby facilitating their removal by ciliary action and coughing. They are believed to achieve this by a reflex irritant effect on the gastric mucosa.

Ipecacuanha:

Ipecacuanha Extract is prepared from the dried underground organs of *Cephalis ipecacuanha* or of *C. acuminata*. It has been used as an expectorant in productive cough in doses of up to about 1.4mg of total alkaloids. It is used in larger doses as an emetic.

Liquorice:

Liquorice is obtained from the dried rhizomes and roots of *Glycyrrhiza glabra*. It is used as a flavouring and sweetening agent. It has demulcent and expectorant properties and has been used in cough preparations. It also has ulcer-healing properties that may result from stimulation of mucus synthesis and mild anti-inflammatory and mineralocorticoid properties associated with the presence of glycyrrhizic acid and its metabolite glycyrrhetic acid, which is an inhibitor of cortisol metabolism. Liquorice may also possess some antispasmodic and laxative properties.

Peppermint Oil:

Peppermint oil is obtained by steam distillation from the fresh overground parts of the flowering plant of *Mentha piperita*. It is an aromatic carminative that relaxes gastrointestinal smooth muscle and relieves flatulence and colic.

It has been used as a flavour and with other volatile agents in preparations for respiratory tract disorders.

Aniseed Oil:

Aniseed oil is a carminative and is mildly expectorant. It is a common ingredient of cough preparations. It is also a flavour.

5.2 Pharmacokinetic properties

Ammonium chloride is absorbed from the GIT. The ammonium ion is converted into urea in the liver, the anion thus liberated in the blood and extracellular fluid causes a metabolic acidosis and decreases the pH of the urine, and this is followed by transient diuresis

Liquorice is a demulcent and mild expectorant. No information is available on the pharmacokinetics of liquorice.

5.3 Preclinical safety data

None.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Methyl Hydroxybenzoate

Lactose

Gelatin

Avicel PH 101

Citric Acid

Dry Pineapple Flavour

Colloidal Silicon Dioxide

Aspartame Powder

Caramel

Magnesium Stearate

6.2 Incompatibilities

None known.

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

Alu/Alu strips containing 10 lozenges per blister placed in a printed carton to give packs of 100 lozenges.

6.6 Special precautions for disposal and other handling

None.

7. APPLICANT/MANUFACTURER

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