

Important information. Please read carefully.

# Colimix<sup>®</sup>

## Syrup

**Relieves infant colic, wind and abdominal discomfort**

### Composition

Each 5 ml contains

Dicyclomine HCl ..... 5 mg

Simethicone ..... 50 mg

Methyl Hydroxybenzoate 0.18% w/v and

Propyl Hydroxybenzoate 0.02% w/v as preservatives.

Ethanol 96% 0.09 ml/5ml

### Indication

Infant colic:

Babies drink very quickly and they swallow much air with their milk; especially when bottle-fed. If the air is not expelled (e.g. by burping), the bubbles get trapped in the digestive system. Painful spasms (colic) develop as the intestines try to expel the bubbles; and the baby cries without stopping. **Colimix** breaks up the bubbles and relaxes the intestinal muscles thus easing the pain and helping baby to burp.

Flatulence (wind) and abdominal discomfort:

In older children and adults, **Colimix** is equally effective in relieving flatulence (wind) and abdominal discomfort due to entrapped gas.

### Pharmacodynamics

Dicyclomine hydrochloride is a tertiary amine antimuscarinic with effects similar to but weaker than those of atropine. It also has a direct antispasmodic action.

Simethicone is a mixture of liquid dimeticones containing finely divided silicon dioxide to enhance the defoaming properties of the silicone. It lowers surface tension and when given by mouth causes bubbles of gas in the gastrointestinal tract to coalesce, thus aiding their dispersion.

### Pharmacokinetics

Dicyclomine is rapidly absorbed after oral dosing with peak plasma concentrations occurring within 1 to 1.5 hours. Dicyclomine is excreted mainly in the urine (nearly 80% of a dose), with a small amount in the faeces (about 8%). The mean elimination half-life for the first 9 hours after a single dose is about 1.8 hours.

### Dosage

For oral administration only.

Unless otherwise prescribed by the physician:

Infants over 6 months : 5 ml before each feed. Do not exceed 4 doses in 24 hours.

Children 4 to 12 years : 5 to 10 ml 4 times daily.

Adults : 10 ml 3 to 4 times daily and at bedtime.

Do not exceed the stated dose.

### Contraindication

Dicyclomine is not recommended for use in infants under the age of six months.

### Precautions

Dicyclomine is an anticholinergic and the usual precautions should be observed in patients with glaucoma, prostatic enlargement, urinary retention, tachycardia, cardiac insufficiency, paralytic ileus, ulcerative colitis or pyloric stenosis. May aggravate oesophageal reflux. The safety of this product in pregnancy has not been fully established and should be carefully assessed by the physician before use.

### Side Effects

Simethicone is physiologically inert, non-absorbable substance and does not cause any side effect. Dicyclomine Hydrochloride, being poorly absorbed, possesses less anticholinergic side effects compared with atropine. The following effects may be observed with high doses: dry mouth, urinary hesitancy and retention, blurred vision, tachycardia, palpitations, flushing and dryness of the skin, constipation, mydriasis, increased ocular tension, loss of taste, headache, nervousness, drowsiness, weakness, suppression of lactation, nausea, vomiting, mental confusion and/or excitement, especially in elderly persons and decreases sweating.

### Symptoms and Treatment of Overdose

In overdosage, the peripheral effects become more pronounced and other symptoms such as hyperthermia, hypertension, increased respiratory rate, and nausea and vomiting may occur. A rash may appear on the face or upper trunk. Toxic doses also cause CNS stimulation marked by restlessness, confusion, excitement, ataxia, incoordination, paranoid and psychotic reactions, hallucinations and delirium, and occasionally seizures. However, in severe intoxication, central stimulation may give way to CNS depression, coma, circulatory and respiratory failure, and death. If a patient presents within an hour of an oral overdose of Dicyclomine hydrochloride the stomach may be emptied or activated charcoal given to reduce absorption. Supportive therapy should be given as required; in particular, hypoxia and hypotension should be corrected. Metabolic acidosis that persists despite correction of hypoxia and adequate fluid replacement may require treatment with intravenous sodium bicarbonate. Arrhythmias are best managed by correction of hypoxia and acidosis; antiarrhythmics should not be given. Diazepam has been used to manage repeated or prolonged convulsions (lorazepam has also been given), and for sedation in agitated adults. Physostigmine has been tried for antimuscarinic poisoning but such use can be hazardous and is not generally recommended.

### Shelf-life

The expiry date is indicated on the packaging.

### Presentation

Sweetly flavoured, orange colour syrup in dispensing packs of 60ml and 90ml.

### Storage

Store below 30°C. Protect from light.

### KEEP OUT OF REACH OF CHILDREN

### JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

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