

Axcel
DICYCLOMINE-S
SYRUP

COMPOSITION :

Each 5 ml contains
 Dicyclomine hydrochloride 5 mg
 Simethicone 50 mg
 0.1% w/v Methylparaben as preservative
 0.01% w/v Sunset Yellow as colorant

PRESENTATION :

Orange coloured and orange flavoured syrup.

INDICATION :

Relief of gastro-intestinal colic, flatulence & abdominal discomfort due to entrapped gas.

MECHANISMS OF ACTION :

Dicyclomine Hydrochloride is a tertiary amine with antimuscarinic effects similar to but weaker than those atropine; it also has a direct anti-spasmodic action. Simethicone lowers surface tension and when administered by mouth causes bubbles of gas in the gastro-intestinal tract to coalesce, thus aiding their dispersion.

PHARMACOLOGY :

Dicyclomine is used in gastro-intestinal spasm, particularly that associated with the irritable bowel syndrome, and is also given in association with antacids as an adjunct in the treatment of peptic ulcer. Simethicone is used to relieve flatulence and abdominal discomfort due to excess gastro-intestinal gas and also used as defoaming agent in radiography or endoscopy of the gastro-intestinal tract.

DOSAGE :

To be taken orally, 15 minutes before meal.
 Adults : 10 - 20 ml, 3 to 4 times a day;
 Children (2-12 years) : 10 ml, 3-4 times daily,
 (6 months to 2 years) : 5 to 10 ml, 3-4 times daily, total daily dose should not exceeding 40 ml.

**SHOULD NOT BE GIVEN TO INFANTS
 YOUNGER THAN 6 MONTHS OF AGE**

CONTRAINDICATIONS :

Should not be given to infants younger than 6 months or age. Contraindicated in patients with closed-angle glaucoma, urinary or GI obstruction, intestinal atony, paralytic ileus, hypersensitivity to Dicyclomine, unstable cardiovascular status in acute hemorrhage and reflux oesophagitis.

SIDE EFFECTS :

Increase of intra-ocular pressure especially in patients with closed-angle glaucoma. Dryness of the mouth with difficulty in swallowing and talking, thirst, reduced bronchial secretions, dilatation of the pupils (mydriasis) with loss of accommodation (cycloplegia) and photophobia, flushing and dryness of the skin, transient bradycardia followed by tachycardia, with palpitations and arrhythmias, and difficulty in micturition, as well as reduction in the tone and motility of gastro-intestinal tract leading to constipation, elevated body temperature and CNS excitation that is caused by the antimuscarinic effect. Occasionally vomiting may also occur.

PRECAUTION :

Due to the risk of provoking hyperpyrexia, it should not be given to patients, especially children when the ambient temperature is high. It should also be used cautiously in patient with fever, asthma, hiatal hernia, serious hepatic or renal disease. Precaution in acute myocardial infarction, hypertension. Elderly and in conditions characterized by tachycardia & in debilitated patients with COPD.

PREGNANCY & LACTATION

The safety in use of Axcel Dicyclomine-S Syrup during pregnancy has not been fully established. Pregnant patients should take with precaution.

SYMPTOMS & TREATMENT FOR OVERDOSAGE :

Symptoms of overdose include: tachycardia, rapid respiration, hyperpyrexia, CNS stimulation marked by confusion, excitement, ataxia and occasionally seizure. Rashes may appear on the face or upper trunk. Overdosage occurred when taken by mouth, the stomach should be emptied. The giving of activated charcoal to reduce absorption has also been suggested. Supportive therapy should be given as required.

DRUG INTERACTIONS :

Anticholinergic activity may be increased by other parasympatholytics. Guenethidine, histamine & reserpine

can antagonise the inhibitory effects of anticholinergics on gastric acid secretion. Antacids may impair absorption.

STORAGE :

Keep container well closed. Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

JAUHI DARI KANAK-KANAK.

SHELF-LIFE :

3 years.

PACKAGE QUANTITIES :

60ml & 100ml in amber PET bottle,
 120ml & 1L in amber glass bottle.

Further information can be obtained from your pharmacist, physician or the manufacturer.



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