



AXCEL[®]
DICYCLOMINE-S
SYRUP

COMPOSITION:

Each 5ml contains
Dicyclomine hydrochloride 5mg
Simethicone 50mg

0.1% w/v Methylparaben as preservative

PRESENTATION:

Orange coloured and orange flavoured syrup.

INDICATIONS:

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

PHARMACOLOGY:

Mechanism 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.

Pharmacokinetics:

Dicyclomine is used in gastrointestinal 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 gastrointestinal gas and also used as defoaming agent in radiography or endoscopy of the gastrointestinal tract.

DOSAGE AND ADMINISTRATION:

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

CONTRAINDICATION:

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

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 debilitate patients with COPD.

Use in Pregnancy and Lactation:

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

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 micturation, 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.

DRUG INTERACTIONS:

Anticholinergic activity may be increased by other parasympatholytics. Guanethidine, histamine & reserpine can antagonise the inhibitory effects of anticholinergics on gastric acid secretion. Antacids may impair absorption.

OVERDOSAGE AND TREATMENT:

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.

STORAGE :

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

**KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK**

PACK

Available in 60ml & 100ml in PET bottle, and 120ml in glass bottle.

QUANTITIES:

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

MAL 19991140AZ

Product Registration Holder & Manufactured by:



Kotra Pharma (M) Sdn. Bhd.
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