SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CYCLOPAM SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Dicycloverine hydrochloride BP	10 mg
Simethicone Emulsion USP Equivalent to Simethicone	40 mg
Colour: Ponceau 4R	

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Solution

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

CYCLOPAM Suspension is indicated in infantile gripes, diarrhoeal colics, billiary colics, renal colics, post-feed vomiting and flatulence

4.2. Posology and method of administration

Children (2-12 years): One 5ml spoonful three times daily or as directed by physician.

4.3.Contraindications

CYCLOPAM Suspension is contraindicated in individual who exhibited hypersensitivity to ingredients of this medication. It should not be given to Infants under 6 months of age. It is also contraindicated in patients with Obstructive uropathy, Obstructive disease of the gastrointestinal tract, Severe ulcerative colitis, Reflux esophagitis, Unstable cardiovascular status in acute hemorrhage, Glaucoma, Myasthenia gravis. Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.4. Special warning and precautions for use

Products containing dicycloverine hydrochloride should be used with caution in any patient with or suspected of having glaucoma or prostatic hypertrophy. Use with care in patients with hiatus hernia associated with reflux oesophagitis because anticholinergic drugs may aggravate the condition. Dicyclomine hydrochloride is contra-indicated in infants under 6 months of age.

4.5. Interaction with other medicinal products and other forms of interaction

The following agents may increase certain actions or side effects of anticholinergic drugs: amantadine, antiarrhythmic agents of Class I (e.g., quinidine), antihistamines, antipsychotic agents (e.g., phenothiazines), benzodiazepines, MAO inhibitors, narcotic analgesics (e.g., meperidine), nitrates and nitrites, sympathomimetic agents, tricyclic antidepressants, and other drugs having anticholinergic activity.
Anticholinergics antagonize the effects of antiglaucoma agents. Anticholinergic drugs in the presence of increased intraocular pressure may be hazardous when taken concurrently with agents such as corticosteroids.
Anticholinergic agents may affect gastrointestinal absorption of various drugs, such as slowly dissolving dosage forms of digoxin; increased serum digoxin concentrations may result. Anticholinergic drugs may antagonize the effects of the drugs that alter gastrointestinal motility, such as metoclopramide. Because antacids may interfere with the absorption of anticholinergic agents, simultaneous use of these drugs should be avoided.
The inhibiting effects of anticholinergic drugs on gastric hydrochloric acid secretion are antagonized by agents used to treat achlorhydria and those used to test gastric secretion

4.6. Fertility, pregnancy and lactation

Pregnancy
Dicyclomine belongs to Pregnancy Category B.
CYCLOPAM Suspension should be used during pregnancy only if clearly needed.

Lactation
Caution should be exercised when CYCLOPAM Suspension is administered to a nursing mother.

4.7. Effects on ability to drive and use machines

Not mentioned

4.8. Undesirable effects

Dicyclomine: In susceptible individuals, dry mouth, thirst and dizziness may occur. On rare occasions, fatigue, sedation, blurred vision, rash, constipation, anorexia, nausea and vomiting, headache and dysuria have also been reported.

Simethicone: No adverse effects have been noted after ingestion.

4.9. Overdose

Symptoms of dicyclomine overdosage are headache, dizziness, nausea, dry mouth, difficulty in swallowing, dilated pupils and hot dry skin. Treatment may include emetics, gastric lavage and symptomatic therapy if indicated.

Overdosage of simethicone would not be expected to cause clinically important effects and no specific treatment is indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

CYCLOPAM Suspension is comprised of antispasmodic agent Dicyclomine HCl and antifoaming agent Simethicone.
Dicyclomine relieves smooth muscle spasm of the gastrointestinal tract. Animal studies indicate that this action is achieved via a dual mechanism: (1) a specific anticholinergic effect (antimuscarinic) at the acetylcholine-receptor sites with approximately 1/8 the milligram potency of atropine (*in vitro*, guinea pig ileum); and (2) a direct effect upon smooth muscle (musculotropic**).**
Physiologically Simethicone is a chemically inert, non-systemic gastric defoaming agent that works by altering the elasticity of interfaces of mucus-embedded bubbles in the gastrointestinal tract. It is not absorbed from the gut. The gas bubbles are thus broken down or coalesced and in this form gas is more easily eliminated through eructation or passing flatus

5.2. Pharmacokinetic properties

Dicyclomine:
Dicyclomine is rapidly absorbed after oral administration, reaching peak values within 60-90 minutes. It is extensively distributed in tissues. The principal route of elimination is via the urine (79.5% of the dose). Excretion also occurs in the feces, but to a lesser extent (8.4%).

Simethicone: Absorption is presumed to be minimal. Presystemic metabolism is unknown as is the half-life, the volume of distribution, plasma protein binding, and secretion in human breast milk

5.3. Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Xanthan gum
Indion 254
Sucrose
Sodium Methyl Hydroxybenzoate
Sodium Propyl Hydroxybenzoate
Liquid Sorbitol (Non Crystallizing)
Saccharin sodium
Essence mixed fruit S-2535 (Bush)
Menthol
Citric acid monohydrate

Colour ponceau 4R supra
Purified water

6.2. Incompatibilities
Not Applicable

6.3 Shelf life
36 Months

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

6.5. Nature and content of the container
30 ml amber PET bottle. One such labelled bottle is packed in a carton along with the pack insert.

6.6. Special precautions for disposal and handling Shake well before use.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESS

Manufacturer name and address:
Indoco Remedies Limited
Indoco Remedies Ltd.
Village Katha, Baddi, Tehsil Nalagarh,
District Solan (H.P.) 173205

Marketing Authorization Holder Name and Address:

Indoco Remedies Limited

Indoco House, 166, C.S.T Road,
Santacruz (E), Mumbai - 400 098, India.

8. MARKETING AUTHORIZATION NUMBER
H2006/692 /R1

9. DATE OF FIRST REGISTRATION /RENEWAL REGISTRATION

16/02/2026

10. DATE OF REVISION OF TEXT
16/02/2026