Summary of Product Characteristics for Pharmaceutical Products

1.Name of the Medicinal Product

COLIMEX DROPS (Dicycloverine Hydrochloride & Simethicone Suspension)

2.Quality and Quantitative Composition

Each ml contains

Dicycloverine Hydrochloride BP … 10 mg

Simethicone USP … 40 mg

Excipients with known effect:

Sorbitol Solution (70%) (Non-Crystallizing) BP 2.653mg/mL

Sucrose BP 430mg/mL

For full list of excipients, see section 6.1.

3.Pharmaceutical Form:

Suspension

4.Clinical Particulars

4.1 Therapeutic indications

Colimex Suspension 10 ml is an 'antispasmodic' (spasm and cramps reliever) agent containing Dicyclomine and Simethicone, primarily used for reducing stomach pain due to spasm, cramps and bloating. Abdominal spasms are the acute condition in which the abdominal muscles (abs), intestine and stomach contracts severely. Stomach spasm can be caused due to muscle strain, dehydration, stomach gas formation, inflammatory bowel diseases (IBD) like Crohn's disease and ulcerative colitis, gastritis (stomach inflammation), pregnancy, constipation, or other gastrointestinal infection

4.2 Posology and method of administration

For oral administration in infants and children between 6 months to 2 years of age: 0.5 to 1 ml (approximately 10 to 20 drops) to be administered 3 to 4 times a day. Or, as directed by the physician.

a. Missed Dose

Give the missed dose of Colimex Drops as soon as you remember. If it is almost the time for the next dose, skip the missed dose. Do not double your dose to make up for the missed dose.

b. Overdose
Seek medical emergency in case of an Colimex Drops overdose.

4.3 Contraindications/Precautions

If your child is allergic to Dicycloverine, simethicone or any other ingredients of the Colimex drops.
Colimex oral drops are not to be given to infants under 6 months of age.

4.4 Special warnings and precautions for use Dicyclomine Hydrochloride General:

Products containing dicyclomine 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 esophagitis because anticholinergic drugs may aggravate the condition. Peripheral and Central Nervous System (CNS): The peripheral effects of dicyclomine hydrochloride are a consequence of their inhibitory effect on muscarinic receptors of the autonomic nervous system. They include 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 the gastrointestinal tract leading to constipation.

Cardiovascular Conditions: Dicyclomine hydrochloride needs to be used with caution in conditions characterized by tachyarrhythmia such as thyrotoxicosis, congestive heart failure, and in cardiac surgery, where they may further accelerate the heart rate. Investigate any tachycardia before administration of dicyclomine hydrochloride. Care is required in patients with coronary heart disease (as ischemia and infarction may be worsened) and in patients with hypertension.

Hepatic and Renal Disease: Should be used with caution in patients with known hepatic and renal impairment.

Simethicone

No special warnings and precautions are needed. Simethicone is apparently non-toxic; no adverse effects reported.

4.5 Interaction with other medicinal products and other forms of interactions Dicyclomine Hydrochloride

Anti-glaucoma agents: Anticholinergics antagonize the effects of anti-glaucoma agents. Anticholinergic drugs in the presence of increased

intraocular pressure may be hazardous when taken concurrently with agents such as corticosteroids. Use of dicyclomine in patients with glaucoma is not recommended. Other drugs with anticholinergic activity:

The following agents may increase certain actions or side effects of anticholinergic drugs including dicyclomine: Amantadine, antiarrhythmic agents of Class I (e.g., quinidine), antihistamines, antipsychotic agents (e.g., phenothiazines), benzodiazepines, monoamine oxidase (MAO) inhibitors, narcotic analgesics (e.g., meperidine), nitrates and nitrites, sympathomimetic agents, tricyclic antidepressants, and other drugs having anticholinergic activity. 3 Other gastrointestinal motilities.

Drugs: Interaction with other gastrointestinal motility drugs may antagonize the effects of
drugs that alter gastrointestinal motility, such as metoclopramide. Effect of antacids: Because antacids may interfere with the absorption of anticholinergic agents including dicyclomine, simultaneous use of these drugs should be avoided. Effect on absorption of other drugs: Anticholinergic agents may affect gastrointestinal absorption of various drugs by affecting on gastrointestinal motility, such as slowly dissolving dosage forms of digoxin; increased serum digoxin concentration may result. Effect on gastric acid secretion: The inhibitory effects of anticholinergic drugs on gastric hydrochloric acid secretion is antagonized by agents used to treat achlorhydria and those used to test gastric secretion.

Simethicone
There are no known reported drug interactions with simethicone.

4.6 Pregnancy and Lactation

Pregnancy:

Epidemiological studies in pregnant women with products containing dicycloverine hydrochloride (at doses up to 40 mg/day) have not shown that dicycloverine hydrochloride increases the risk of foetal abnormalities if administered during the first trimester of pregnancy.

Fertility:

Reproduction studies have been performed in rats and rabbits at doses of up to 100 times the maximum recommended dose (based on 60 mg per day for an adult person) and have revealed no evidence of impaired fertility or harm to the foetus due to dicycloverine. Since the risk of teratogenicity cannot be excluded with absolute certainty for any product, the drug should be used during pregnancy only if clearly needed.

Breast-feeding:

It is not known whether dicycloverine is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when dicycloverine is administered to a nursing mother.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side-effects seldom occur with dicycloverine tablets. However, 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.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions to report any suspected adverse reactions to the National Regulatory Authority.

4.9 Overdose

Overdosing can cause headaches, dizziness, nausea, dry mouth, swallowing difficulties, and dilated pupils. If you think you've taken more than the recommended dosage, call your doctor or go to the nearest hospital right away.

5 Pharmacological Properties

5.1 Pharmacodynamic properties Dicyclomine Hydrochloride

Dicyclomine is an anti-spasmodic and anti-muscarinic agent. Dicyclomine relieves smooth muscle spasm of the GI, biliary, and ureteric tracts.

Simethicone

Simethicone is an anti-flatulent agent. Simethicone does not reduce the quantity of gas in the digestive tract; it only increases the rate at which it exits the body. Simethicone does not prevent the formation of gas from swallowed air or from being created by intestinal bacteria.
Pharmacodynamic properties

5.2 Pharmacokinetic properties Dicyclomine Hydrochloride

Dicyclomine is rapidly absorbed after oral administration, reaching peak values within 60 to 90 minutes. Mean volume of distribution for a 20 mg oral dose of dicyclomine is approximately 3.65 l/kg, suggesting extensive tissue penetration. The principal route of elimination of dicyclomine is via the urine (79.5% of the dose). Excretion also occurs in the feces, but to a lesser extent (8.4%). There are two phases of elimination, the first with a shorter half-life of 1.8 hours, and a second phase with a longer half-life.

Simethicone

Simethicone is locally acting and is not absorbed. It is eliminated unchanged in feces.

5.3 Preclinical safety data

safety data: None stated

6 Pharmaceutical Particulars

6.1 List of excipients

Inactive

Sorbitan Monostearate (Span 60/ Arlacel 60) BP
Polysorbate 60 (Tween 60) BP
Methacrylic acid Polymer with
Divinyl Benzene & Acrylic acid (Indion 204) BP
Sorbitol Solution (70%) (nonCrystallizing) BP
Glycerol BP
Guar BP
Sodium Methylparaben (Sodium Methy Hydroxybenzoate) BP
Sodium Propylparaben (Sodium Propyl Hydroxybenzoate) BP
Disodium Edetate BP
Sucrose BP
Neotame USP/NF
Magnesium Aluminium Silicate (Veegum)
USP/NF 13.Polyoxyl 40Hydrogenated
Castor
Oil (Cresmer RH 40 / Cremophor RH 40) USP
Sodium Hydroxide BP
Sunset Yellow FCF IH
Fruit Cocktail ID 21244 {Quest} IH
Lychee Global
(Firmenich)IH
18.Purified water BP

6.2 Incompatibilities:

Not applicable

6.3 Shelf-Life

3 years.

6.4 Special Precautions for storage

Store below 30°C.
Protect from light.
Do not freeze,
Keep out of the reach of children.

6.5 Nature and Content of container

Colimex is available in a bottle of 10 ml (with dropper).

6.6 Special precautions for disposal and other handling

Store below 30°C.
Protect from light.
Do not freeze,
Keep out of the reach of children.

7. Marketing authorization Holder

Wallace Pharmaceuticals Pvt Ltd
3rd Floor, Dempo Trade Centre Bldg., Patto Plaza, EDC Complex, Panaji, Goa - 403001, India.

8. Marketing Authorization Numbers:

H2024/CTD11236/24575

9. Date of first authorization/renewal of the authorization:

23/06/2016

10. Date of revision of the text:

25.05.2022