Not to be sold by retail without the prescription of a Registered Medical Practitioner

Dicyclomine Hydrochloride & Simethicone Suspension

MEFTAL-SPAS® Suspension

COMPOSITION

Each 5 ml contains:
Dicyclomine Hydrochloride IP ……..……..... 10 mg.
Simethicone Emulsion USP eq. to Simethicone ……..….. 40 mg.
Flavoured syrup base ……. q.s.

DOSAGE FORM

Oral liquid.

INDICATIONS

MEFTAL-SPAS Suspension is used for the relief of infantile colic, gastrointestinal tract (GI) spasm, flatulence and abdominal discomfort due to excess gas formation in disorders such as dyspepsia and gastro esophageal reflux disease (GERD).

DOSE AND METHOD OF ADMINISTRATION

For oral administration.

- **Infants and children between 6 months to 2 years:** 2.5 to 5 ml to be administered 3 to 4 times a day.
- **Children between 2 to 12 years:** 5 ml to be administered 3 times daily.
- **Adults and adolescents:** 5 to 10 ml to be administered 3 times daily.

Or, as prescribed by the Physician.

USE IN SPECIAL POPULATIONS

Pregnant Women

Dicyclomine: Pregnancy Category B; Simethicone: Pregnancy Category C.
Epidemiological studies in pregnant women with products containing dicyclomine hydrochloride (at doses up to 40 mg/day) have not shown that dicyclomine hydrochloride increases the risk of fetal abnormalities if administered during the first trimester of pregnancy. Safety of simethicone during pregnancy has not been adequately evaluated. Simethicone is not expected to harm an unborn baby. Due to lack of safety in human trials, this product should be used during pregnancy only if clearly needed and under medical supervision.

Lactating Women

It is not known whether simethicone passes into breast milk or if it could harm a nursing baby. Dicyclomine has been reported to be excreted in human milk. Use of dicyclomine is

contraindicated in nursing mothers. Because of the potential for serious adverse reactions in nursing infants, MEFTAL-SPAS suspension is contraindicated for use during breast-feeding.

Paediatric Patients
MEFTAL-SPAS Suspension (due to its dicyclomine content) is contraindicated in infants less than 6 months of age. For dosage in children above 6 months, please refer 'DOSE AND METHOD OF ADMINISTRATION' section.

Geriatric Patients
Generally no dose adjustment is required in elderly patients with normal hepatic and renal function. Dicyclomine is known to be substantially (up to 79.5%) excreted by the kidney, thus, risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

CONTRAINDICATIONS
MEFTAL-SPAS Suspension is contraindicated in the following:

- Known hypersensitivity to dicyclomine or to simethicone or to any excipient of the formulation.
- Infants under 6 months of age.
- Breast-feeding women.
- Obstructive uropathy.
- Obstructive disease of the GI 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.

WARNINGS AND PRECAUTIONS
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: 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. Dicyclomine is primarily eliminated by the kidney, thus dosage adjustment is usually required in patients with severe renal impairment.

Simethicone

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

DRUG 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.

Gastrointestinal Motility Drugs (Metoclopramide): 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 (Digoxin): 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 are antagonized by agents used to treat achlorhydria and those used to test gastric secretion.

Simethicone

There are no known reported drug interactions with simethicone.

UNDESIRABLE EFFECTS

Dicyclomine Hydrochloride

Side-effects seldom occur with dicyclomine. However, in susceptible individuals, the following adverse effects have been reported:

Gastrointestinal disorders: Abdominal distension, abdominal pain, constipation, dry mouth, dyspepsia, nausea, vomiting.

General disorders and administration site conditions: Fatigue, malaise.

Immune system disorders: Drug hypersensitivity including face edema, angioedema, anaphylactic shock.

Cardiac disorders: Palpitations, tachyarrhythmias.

Eye disorders: Cycloplegia, mydriasis, blurred vision.

Nervous system disorders: Dizziness, headache, hallucinations, insomnia, somnolence, syncope.

Psychiatric disorders: Confusional state, nervousness.

Reproductive system and breast disorders: Suppressed lactation.

Respiratory, thoracic, and mediastinal disorders: Dyspnea, nasal congestion.

Skin and subcutaneous tissue disorders: Allergic dermatitis, erythema, rash.

Simethicone

Simethicone may cause diarrhea, nausea, vomiting, and headache. Seek immediate medical attention if any of the following allergic symptoms/reactions occur: Hives; difficulty breathing; swelling of face, lips, tongue, or throat.

OVERDOSE

Dicyclomine Hydrochloride

Symptoms of dicyclomine overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot dry skin, dizziness, dryness of the mouth, difficulty in swallowing, and CNS stimulation. A curare-like action may occur (i.e., neuromuscular blockade leading to muscular weakness and possible paralysis).

Treatment should consist of gastric lavage, emetics, and activated charcoal. Sedatives (barbiturates/benzodiazepines) may be used for management of overt signs of excitement. If indicated, an appropriate parenteral cholinergic agent may be used as an antidote.

Simethicone

Simethicone is apparently non-toxic; no adverse effects reported. Seek emergency medical attention in case of overdose.

PHARMACODYNAMICS

Dicyclomine Hydrochloride

Dicyclomine is an anti-spasmodic and anti-muscarinic agent. Dicyclomine relieves smooth muscle spasm of the GI, biliary, and ureteric tracts. This action of dicyclomine is achieved via a dual mechanism:

1. A specific anticholinergic effect (antimuscarinic) at the acetylcholine-receptor sites with approximately $\frac{1}{8}^{th}$ the milligram potency of atropine.
2. A direct spasmolytic effect upon smooth muscles (musculotropic) of intestine, bile duct, ureters, and uterus.

Simethicone

Simethicone is an anti-foaming agent that decreases the surface tension of gas bubbles, causing them to combine into larger bubbles in the stomach that can be passed more easily by burping. 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.

PHARMACOKINETICS

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.

INCOMPATIBILITIES

None known.

SHELF-LIFE

Expiry date as mentioned on the product pack.

PACKAGING INFORMATION

30 ml bottle with measuring cup.

STORAGE AND HANDLING INSTRUCTIONS

Store in a cool place protected from light.
Keep out of reach of children.

Last updated: March 2020