Lagaspasm®

Dicycloverine HCl/Phenobarbital

Composition:
Each tablet contains Dicycloverine hydrochloride 20 mg, Phenobarbital 15 mg, Excipients q. s.

Properties
Lagaspasm is the combination of a barbiturate and of a synthetic anticholinergic. The latter, Dicycloverine hydrochloride, has the same action on the gastro-intestinal tract as atropine, but at the usual therapeutic doses, it is devoid of the mydriatic, secretory and cardiac effects of atropine. Dicycloverine hydrochloride has a sedative action on smooth muscles and on the parasympathetic system. The barbiturate in Lagaspasm is Phenobarbital, a sedative of the central nervous system. In combination with the anticholinergic, it develops an optimal effect for the relief of a great number of troubles of spastic origin.

Indications
Lagaspasm is indicated in functional disorders of gastro-intestinal tract, such as cramps resulting from hypermotility of the small and large intestine, irritable colon and spastic constipation. It is also indicated in primary dysmenorrhoea, pylorospasm and biliary tract dysfunction.

Dosage
Adults: 1 tablet three times daily before or after meals.

Contraindications
Lagaspasm is contraindicated in patients with known Phenobarbital sensitivity or a history of manifest or latent porphyria. Caution should be exercised when Lagaspasm is administered to a nursing woman since small amounts of Phenobarbital are excreted in the milk. Also, Dicycloverine is contraindicated in infants less than 6 months of age. Safety and effectiveness in pediatric patients have not been established.

Warnings and Precautions
Phenobarbital may be habit forming. Tolerance and psychological and physical dependence may occur with continuing use. Therefore, Lagaspasm should be administered with caution to patients, who are mentally depressed, have suicidal tendencies, or a history of drug abuse. Elderly or debilitated patients may react to Phenobarbital with marked excitement, depression, and confusion.
In patients with hepatic damage, Lagaspasm should be administered with caution and initially reduced doses. Phenobarbital should not be administered to patients showing the premonitory signs of hepatic coma.
Investigate any tachycardia before administration of Lagaspasm, since Dicycloverine hydrochloride may increase the heart rate. Use with caution in patients with Autonomic neuropathy, Hepatic or renal disease, Ulcerative colitis, Hyperthyroidism, Hypertension, Coronary heart disease, Congestive heart failure, Cardiac tachyarrhythmia, Hiatal hernia and known or suspected prostatic hypertrophy.

Side effects
Symptoms of acute intoxication with Phenobarbital include unsteady gait, slurred speech, and sustained nystagmus. Mental signs of chronic intoxication include confusion, poor judgment, irritability, insomnia and somatic complaints.
Controlled clinical trials have provided information for reported adverse effects. The following adverse reactions have been reported with Dicycloverine hydrochloride. Adverse reactions included below have been reported for pharmacologically similar drugs with anticholinergic/antispasmodic action.
Gastrointestinal: Dry mouth nausea, vomiting, constipation, bloated feeling, taste loss, anorexia.
Central Nervous System: Dizziness, lightheadedness, tingling, headache, drowsiness, weakness, nervousness, numbness, mental confusion and/or excitement (especially in elderly persons), dyskinesia, lethargy, syncope, speech disturbance, insomnia.
Ophthalmologic: Blurred vision, diplopia, mydriasis, cycloplegia, increased ocular tension.
Dermatological/Allergic: Rash, urticaria, itching and other dermal manifestations; severe allergic reaction or drug idiosyncrasies including anaphylaxis.
Genitourinary: Urinary hesitancy, urinary retention.
Cardiovascular: Tachycardia, palpitations.
Respiratory: Dyspnea, apnea, asphyxia.
Other: Decreased sweating, nasal stuffiness or congestion, sneezing, throat congestion, impotence, suppression of lactation.
Dicycloverine may produce drowsiness or blurred vision. Therefore, the patients taking Lagaspasm should be warned not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery or performing hazardous work while taking this drug. Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with this drug would be inappropriate and possibly harmful.
Psychosis has been reported in sensitive individuals given anticholinergic drugs. CNS signs and symptoms include confusion, disorientation, short-term memory loss, hallucinations, dysarthria, ataxia, coma, euphoria, decreased anxiety, fatigue, insomnia, agitation and mannerisms. These CNS signs and symptoms usually resolve within 12 to 24 hours after discontinuation of the drug.

Pregnancy and Lactation
Phenobarbital can cause fetal damage when administered to a pregnant woman. Retrospective case-controlled studies have suggested a connection between the maternal consumption of Phenobarbital and higher than expected incidence of fetal abnormalities. Following oral administration, Phenobarbital readily crosses the placental barrier and is distributed throughout fetal tissues with highest concentrations found in the placenta, fetal liver and brain. Dicycloverine has also been reported to be excreted in human milk; therefore Lagaspasm is contraindicated in nursing mothers.

Overdose
The signs and symptoms of overdosage 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 (e.g., short-acting 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.

Storage
Store at room temperature (15-25)°C in the original packaging. Keep out of the reach of children. The preparation is stable up to the expiry date (EXP) shown on the commercial pack.

Packing
A box containing 20 tablets.

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Lagap SA, 6943 Vezia / Switzerland