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AMMENDED
Order of the Ministry of
Health of Ukraine
20.11.2018 № 2142

INSTRUCTION
for medical use

GAZOSPAZAM®

***Composition*:**
active substance: simethicone, dicycloverine hydrochloride;
1 tablet contains simethicone 125 mg, dicycloverine hydrochloride 20 mg;
excipients: magnesium-aluminum silicate, lactose monohydrate, microcrystalline cellulose, calcium hydrogen phosphate, stearic acid, colloidal anhydrous silica, crospovidone, povidone K29/32, Opadry II 85G 54275 pink: iron oxide red (E 172), lecithin, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide (E 171).

Pharmaceutical form. Coated tablets.
Main physico-chemical properties: oval, biconvex, smooth on both sides pink coated tablets.

Pharmacotherapeutic group**.**
Spasmolytic and anticholinergic agents in combination with other drugs. Spasmolytics in combination with other drugs.
Code ATC A03E D.

Pharmacological properties.
Pharmacodynamics.
Gazospazam® is a combination drug that combines two medicines: dicycloverine hydrochloride and simethicone.
Dicycloverine hydrochloride has antispasmodic effect (relieves spasms of smooth muscle in the gastrointestinal tract, abdominal pain associated with this spasm or stretching the walls of the digestive tract) and antisecretory effect on the excretory glands. The effect of dicycloverine is reached due to its specific anticholinergic (antimuscarinic) effect on cholinergic receptors, as well as direct spasmolytic effect on smooth muscles. Studies have shown that dicycloverine is equally effective in acetylcholine and barium chloride-induced spasms. The effect of atropine in barium chloride induced spasm is 200 times weaker than its effect in acetylcholine-induced spasm. Mydriatic action of dicycloverine and its effect on salivary glands secretion are insignificant compared to the effect of atropine (1/500 and 1/300, respectively).
Simethicone is a surface-active substance, defoamer. The mechanism of action is based on lowering the surface tension of gas bubbles, which contributes to free removal of gases from the gastrointestinal tract or their absorption by the intestinal wall. Simethicone improves the quality of roentgenograms and sonograms, provides better distribution of contrast agents in the intestinal mucosa.
Pharmacokinetics.
Dicycloverine hydrochloride after oral intake is rapidly absorbed in the gastrointestinal tract, the maximum plasma concentration is reached after 60-90 minutes; it is excreted mostly with the urine (79.5%0 of the

administered dose), partly – with feces (8.4%). Mean half-life is 1.8 hours. Mean volume of distribution is 3.65 l/kg.
Simethicone is a physiologically and chemically inert substance; it is not absorbed and is excreted intact after passing through the digestive tract.

Clinical characteristics.

Indications.

Treatment of conditions accompanied by spasms of smooth muscles of the gastrointestinal tract and flatulence, as well as the associated abdominal pain. Treatment of spastic conditions of the gastrointestinal tract, including colitis, intestinal colic, irritable bowel syndrome, spastic constipation. As an extra treatment for organic diseases of the gastrointestinal tract in colitis, diverticulitis, enteritis, gastritis, peptic ulcers.

Contraindications.

Hypersensitivity to the components of the drug.
Obstructive diseases of the gastrointestinal tract, paralytic ileus, pyloric stenosis of the gastrointestinal tract with obstruction, severe ulcerative colitis, reflux esophagitis.
Obstructive diseases of the biliary tract.
Renal failure, obstructive diseases of the urinary tract, prostate adenoma with difficult urination.
Glaucoma.
Myasthenia gravis.
Thyrotoxicosis.
Heart failure, unstable status of the cardiovascular system in acute hemorrhages

Interaction with other medicinal products and other forms of interaction.

Amantadine, antiarrhythmic drugs of class I (e.g., quinidine), antihistamines, antipsychotics (e.g. phenothiazines), benzodiazepines, MAO inhibitors, narcotic analgesics (e.g., meperidine), nitrates and nitrites, sympathomimetic agents, tricyclic antidepressants and other drugs with anticholinergic activity may exacerbate the effects or side effects of dicycloverine.
Anticholinergic drugs may neutralize the effect of antiglaocomatous drugs, the drug should be used with caution in increased intraocular pressure and concomitant use of corticosteroids.
Anticholinergic agents may alter absorption in the gastrointestinal tract of some medications, including long-acting digoxin, which may result in increased concentrations of digoxin in the blood serum.
Dicycloverine may neutralize the effect of drugs that alter the motility of the gastrointestinal tract, such as metoclopramide.
Since antacids may reduce the absorption of anticholinergic drugs, avoid concomitant administration.
Inhibitory effect of anticholinergic drugs on the secretion of hydrochloric acid in the stomach may neutralize the drugs used to treat achlorhydria and study of gastric secretion.

Administration details.

At high ambient temperature during the drug therapy, overheating of the body is possible (elevated body temperature and heat stroke due to reduced sweating). If corresponding symptoms appear, discontinue the drug and seek medical attention.
Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In such cases, drug treatment is inadequate, and possibly harmful.
In persons with individual hypersensitivity to the anticholinergic drugs, the drug may cause such effects on the central nervous system confusion, disorientation, ataxia, increased fatigue, or vice versa - euphoria, excitement, insomnia, affective state. Usually these symptoms disappear within 12-24 hours after discontinuation of the drug.
Gazospazam® should be used with caution in patients with autonomic neuropathy, liver disease or kidney disease, ulcerative colitis (receiving high doses may cause paralytic ileus and development or exacerbation of serious complications such as toxic megacolon), arterial hypertension coronary heart disease, congestive heart failure, tachyarrhythmia, tachycardia, hiatal hernia and prostate hypertrophy.
Excipients. The drug contains lactose. If you have a known intolerance to some sugars, consult your doctor before taking this medicinal agent.

Use during pregnancy or breast feeding.
Safety of treatment with dicycloverine and simethicone during pregnancy is not established, therefore, the drug should not be used in pregnant women.
Since dicycloverine hydrochloride penetrates into the breast milk, the medicinal product should not be used during breast feeding.

Influence on velocity reactions in driving motor transport or operating other machines.
Dicycloverine hydrochloride may cause somnolence and blurred vision, therefore, it is not recommended to drive vehicles and use complicated mechanisms that require high velocity of psychomotor reactions.

Dosage and administration.
Dosage for adults and children over 12 years: 1 tablet 4 times per day; the maximum daily dose is 4 tablets.
The drug is recommended to take before or after a meal. It is not recommended to take the drug longer than 5 days.

Children.
Do not use in children under 12 years old.

Overdose.
Symptoms: headache, nausea, vomiting, dry mouth, difficult swallowing, blurred vision, dilated pupils, hot and dry skin, dizziness, tachycardia, changes in respiratory rate, psychomotor agitation. Curariform action is possible (neuromuscular blockade, feeling of weakness in muscles and paralysis).
Treatment: symptomatic, during the first hours it is recommended to induce vomiting, conduct gastric lavage.

Adverse reactions.
The following side effects are related to the class of anticholinergic drugs, not all of them have been observed when using dicycloverine hydrochloride:
Digestive system: dry mouth, loss of taste, anorexia, nausea, vomiting, dyspepsia, feeling of bloating, abdominal pain, constipation.
Central nervous system: tinnitus, headache, drowsiness, weakness, anxiety, psychosis, numbness, dizziness, coma, confusion and/or agitation (especially in elderly patients), dyskinesia, insomnia, disorientation, short-term memory loss, hallucinations, dysarthria , ataxia, euphoria, inappropriate emotional reactions (symptoms reduce 12-24 hours after dose reduction).
Organs of vision: blurred vision, double vision in eyes, dilated pupils, paralysis of accommodation, increased eye pressure (short atropine-like effects that expire after discontinuation of dicycloverine).
Skin/allergic reactions: hypersensitivity reactions, including allergic dermatitis, rash, urticaria, erythema, drug idiosyncrasy, angioedema, anaphylactic shock.
Genitourinary system: difficult urination, urinary retention.
Cardiovascular system: tachycardia, palpitation.
Respiratory system: breathlessness, apnea, nasal congestion.
Other effects: decreased sweating, nasal congestion, sneezing, swelling of the mucous membrane of the throat, suppression of lactation.

Shelf-life.
2 years.

Storage conditions.
Store in the original package at a temperature NMT 25°C.
Keep it out of reach of children.

Package.
7 tablets are in a blister; 2 blisters are in a carton box.
15 tablets are in a blister; 1, 2 or 4 blisters are in a carton box.

Condition of supply.
Without prescription.

Manufacturer.
“KUSUM PHARM” LTD.

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40020, Ukraine, Sumy Oblast, Sumy, Skryabina Str., 54.

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