INSTRUCTION
for medical use of medicinal product
LEKDONA®

Composition:
active ingredient: belladonna extract dense;
1 suppository contains: 0.015 g (15 mg) belladonna extract dense ((4.8-5.2) : 1) (Belladonnae extractum spissum); extractant 20 % (v/v) ethanol)) (in recalculation on alkaloids 0.00023 g);
excipients: phenol, hard fat

Pharmaceutical form. Rectal suppositories.
From white-creamy to light brown, bullet-shaped suppositories. Presence of bloom on the surface of the suppository is allowed.

Name and location of manufacturer.
Joint Stock Company «Lekhim-Kharkiv»
Ukraine, 61115, Kharkiv region, Kharkiv, Severyna Pototskoho street, building 36.

Pharmacotherapeutic group. Agents for treatment of hemorrhoids and anal fissures for topical use. ATC Code C05A X.

The drug is used for the topical treatment of hemorrhoids. It has analgesic, anti-inflammatory and anti-spasmodic action. Belladonna extract has a cholinolytic effect, reduces intestinal muscle spasms and reduces intestinal motility.

Indications.
Hemorrhoids, anal fissures.

Contraindications.
Hypersensitivity to belladonna or other components of the drug. Cardiovascular diseases when increased heart rate may be undesirable: atrial fibrillation, tachycardia, congestive heart failure, coronary heart disease, mitral stenosis or severe hypertension. Glaucoma. Urine retention or a tendency towards it. Myasthenia. Gastrointestinal disorders accompanied by obstruction. Hyperthermia syndrome. Thyrotoxicosis. Acute bleeding.

Special warnings and precautions for use.
Use with caution in patients with hypertrophy of the prostate without urinary tract obstruction, Down’s syndrome, cerebral palsy, hepatic and renal insufficiency and reflux esophagitis; hiatal hernia combined with reflux esophagitis, inflammatory bowel disease including ulcerative colitis and Crohn's disease, megacolon, patients with xerostomia, elderly or debilitated patients, chronic lung disease without reversible obstruction, chronic lung diseases accompanied by lower production of sputum and difficult discharge, especially debilitated patients with vegetative (autonomic) neuropathy and brain damage.

Use during pregnancy or lactation.
During pregnancy and lactation the drug can be prescribed by a doctor only if the expected benefit to the mother outweighs the potential risk to the fetus/baby.

Effects on ability to drive and use machines.
During treatment patients are advised to refrain from driving or work which requires special attention and accurate coordination.

Paediatric patients.
There are no data on the safety and efficacy of the drug in children.

Posology and method of administration.
Adults should administer 1 suppository 2-3 times daily, rectally. The drug can be used more often if necessary, but not more than 10 suppositories daily.
The duration of treatment is determined by a doctor individually taking into account the course and severity of the disease, achieved therapeutic effect and general treatment strategy. A recommended duration of treatment course is 5-7 days.

Overdose.
Symptoms: increased manifestations of adverse reactions, nausea, vomiting, tachycardia, low blood pressure, agitation, irritability, tremors, convulsions, insomnia, drowsiness, hallucinations, hyperthermia, central nervous system depression and suppression of the respiratory and vasomotor center activity.
Treatment. Gastric lavage, parenteral administration of cholinomimetics and anticholinesterases. Treatment is symptomatic.

Undesirable effects.
Gastrointestinal disorders: dry mouth, thirst, dysgeusia, dysphagia, reduced intestinal motility up to atony, reduced tonicity of the bile ducts and gall bladder.
Kidney and urinary tract disorders: difficulty in urinating and urine retention.
Cardiac disorders: palpitations; arrhythmia including extrasystole; myocardial ischemia.
Vascular disorders: flushing, hot flushes.
Neurological disorders: headache, dizziness.
Eye disorders: mydriasis, photophobia, paralysis of accommodation, increased intraocular pressure.
Respiratory, thoracic and mediastinal disorders: decreased secretory activity and bronchial tone leading to the formation of viscous mucus which is difficult to cough up.
Skin and subcutaneous tissue disorders: skin rash, urticaria, exfoliative dermatitis, flushing.
Immune system disorders: anaphylactic reaction, anaphylactic shock.
Other: decreased sweating, dry skin, dysarthria.

Interaction with other medicinal products and other forms of interaction
Combination with monoamine oxidase inhibitors can cause cardiac arrhythmias; with quinidine and novocainamide – summation of cholinolytic effects. It may reduce the duration and strength of narcotics and reduce the analgesic effects of opiates.
In combination with dimedrol or diprazine the effect of the drug is enhanced; with nitrates, haloperidol, corticosteroids for systemic use – there is the likelihood of increased intraocular pressure increases; with sertraline - depressive effects of both drugs are enhanced; with spironolactone and minoxidil – effects of spironolactone and minoxidil are reduced; with penicillins – effects of both drugs are enhanced; with nizatidine – action of nizatidine is enhanced; with ketoconazole – absorption of ketoconazole is reduced; with ascorbic acid and attapulgite – atropine effect is reduced; with pilocarpine – pilocarpine effects for the treatment of glaucoma are reduced; with oxprenolol – antihypertensive effect of the drug is reduced. Under the influence of octadinum the hyposecretory action of atropine which reduces the effects of M-cholinomimetics and anticholinesterases is reduced. Combination with sulfanilamide drugs increases the risk of kidney damage; with formulations containing potassium – intestinal ulcers are possible; with NSAIDs – increased risk of stomach ulcers and bleeding.

Drug activity may be increased by concomitant use of other drugs with antimuscarinic effects: M-anticholinergics, anti-parkinsonian drugs (amantadine), muscle relaxants, certain antihistamines, butyrophenones, phenothiazines, disopyramides, quinidine and tricyclic antidepressants, non-selective inhibitors of monoamine reverse neuronal capture.
Inhibition of motility by atropine may alter the absorption of other drugs.

Shelf-life. 3 years.

Storage. Store at temperature not exceeding 25 °C. Keep away from children.

Packaging. 5 suppositories in a blister; 2 blisters in a pack.

Prescription status. Without prescription.

Date of last revision.