INSTRUCTION
for medical use
of medicinal product
LEKSADYL®

Composition:
active ingredient: bisacodyl;
1 suppository contains 0.01 g (10 mg) of bisacodyl;
excipients: colloidal silicon dioxide, hard fat.

Dosage form. Rectal suppositories.
Main physicochemical properties: white or cream-colored bullet-shaped suppositories.

Pharmacotherapeutic group. Contact laxatives.
ATC code A06A B02.

Pharmacological properties.
Pharmacodynamics. The drug causes irritation of intestinal receptor apparatus, exerts direct effects on intestinal mucosa, enhances its peristalsis and increases mucus secretion in large intestine. The onset of action occurs within the first hour.
Pharmacokinetics. Bisacodyl is a laxative stimulating large intestine peristalsis by the way of irritating effects on mucosa or direct stimulation of nerve endings in submucous and mucous nervous interlacement.
Bisacodyl is poorly absorbed from gastrointestinal tract and affects electrolyte absorption itself. As a result, increased osmotic pressure in intestinal lumen allows retaining more water, which results in softening of feces and promotion of their passage in large intestine. Besides, the volume of feces increases, which stimulates peristalsis and promotes defecation.
Large intestine bacterial enzymes metabolize bisacodyl to the active compound diphenol, subject to conjugation during hepatic first pass with glucuronic or sulfuric acid, which returns to the intestine via enterohepatic circulation. This process prolongs the drug effect.
Bisacodyl absorption following intrarectal administration is minimal. Absorbed Bisacodyl is subject to deacetylation in liver with formation of phenol derivative subsequently eliminated with urine. The portion remaining in large intestine is eliminated with feces.

Clinical particulars.
Therapeutic indications.
Short-term symptomatic therapy of constipations, including ordinary constipations and chronic constipations in bed-bound patients and elderly patients, before diagnostic procedures, surgical and obstetric interventions, as well as during pre- and postoperative periods.

Contraindications.
Enterostasis; intestinal obstruction; acute diseases of abdominal organs including appendicitis and acute inflammatory intestinal diseases; peritonitis; stomachache; nausea and vomiting of unknown etiology; constricted hernia; gastrointestinal hemorrhages: spastic constipation; intestinal carcinoma; colitis; acute proctitis; acute hemorrhages; rectal diseases; uterine hemorrhages; cystitis; severe dehydration; anal fissures or ulcerative proctitis with mucous membrane affection; hypersensitivity to bisacodyl and other drug ingredients.

Interaction with other medicinal products and other forms of interaction.
Leksadyl® enhances effects of cardiac glycosides due to decreased serum potassium levels. It also enhances kaliuretic effects of diuretics and glucocorticoids.

Administration details.

As well as other laxatives, Leksadyl® should not be used on permanent basis for more than 5 days without identifying constipation causes. Long-term and excessive use of the drug may result in electrolyte and fluid balance disorders, as well as hypokalemia. Long-term use may cause formation of habituation, when defecation act is possible only after use of laxative.
Frequent use of Leksadyl® in elderly patients may enhance asthenia, cause orthostatic hypotension and coordination disorders related with electrolyte loss. The drug may decrease serum potassium levels.
Dizziness and fainting may occur during defecation; defecation syncope and vascular response may appear in abdominal pain, which can be related with constipation inducing the use of laxative.
There were individual reports of abdominal pain and diarrhea with blood admixtures observed during the use of Leksadyl®; their cause may be ischemia of intestinal mucosa.
The suppositories are not recommended for use by patients with anal fissures, proctitis, and ulcerated hemorrhoids, as this may result in pain feelings and local irritation. The drug should not be used in patients with obstructive intestinal diseases or acute conditions such as appendicitis, as well as patients with intestinal inflammatory diseases.

Pregnancy and lactation.
Leksadyl® is not recommended for use during pregnancy, especially in trimester I, except for the cases when expected benefits for the mother exceed potential risks for the fetus; it may be used only at doctor's prescription. Controlled clinical studies involving pregnant women were not conducted in sufficient number.
Leksadyl® is not recommended for use during lactation, except for the cases when expected benefits for the mother exceed potential risks for the fetus; it may be used only at doctor's prescription. It is unknown whether bisacodyl is excreted with breast milk.

Effects on ability to drive and use machines.
The drug does not affect the response rate during driving or operating machinery.

Posology and method of administration.
Before using the suppository, it is necessary to:
– tear off one suppository in primary package along blister package perforation line;
– pull the film edges tearing it apart and release the suppository from the primary package.
The drug is intended for rectal administration.
Leksadyl® should be used for treatment of adult patients only: 1 suppository once a day, usually in the morning. The treatment course lasts for not more than 7 days.

Children.
The drug is not used in children.

Overdose.
Use of Leksadyl® in high doses may result in diarrhea, abdominal spasms, and clinically relevant potassium and electrolyte loss. Intestinal atony and congestive inflammation of rectum may occur sometimes.
Long-term use of laxatives may cause chronic diarrhea, abdominal pain, hypokalemia, secondary hyperaldosteronism and nephrolithiasis. As a consequence of hypokalemia, renal tubule damage, metabolic alkalosis, and muscular weakness events were reported.
Treatment: replacement therapy with fluids and electrolyte imbalance correction (especially hypokalemia).

Adverse reactions.
Immune system disorders: hypersensitivity and allergic reactions including angioedema and anaphylactic reactions.
Gastrointestinal tract disorders: discomfort, pain, abdominal spasms, nausea and diarrhea (with a potential of causing excessive loss of fluids and electrolytes, especially potassium, most frequently

in cases of long-term use or overdose); vomiting, proctitis, rectal mucosa inflammation, intestinal atony, hypokalemia; local irritation of anal area (pain, burning, hemorrhage); colitis.
Muscular weakness, convulsions, and arterial hypotension may develop as a consequence of dehydration.

Shelf life. 3 years.

Storage conditions.
Keep away from children. Store in original package at temperature not exceeding 25 °C.

Package. 5 suppositories in a blister, 2 blisters in a pack.

Dispensing category. Without prescription.

Manufacturer. Joint Stock Company «Lekhim-Kharkiv».

Manufacturer's location and place of business.
Ukraine, 61115, Kharkiv region, Kharkiv, Severyna Pototskoho street, building 36.

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