

PACKAGE LEAFLET
for medical use of medicinal product

BISACODYL-DARNITSA

Qualitative and quantitative composition.

Active substance: bisacodyl;

1 tablet contains bisacodyl 5 mg;

Excipients: potato starch, lactose monohydrate, cellulose microcrystalline, povidone, calcium stearate, methacrylic acid - ethyl acrylate copolymer dispersion, talc, titanium dioxide (E 171), polyethyleneglycol, quinoline yellow (E 104).

Pharmaceutical form. Coated gastro-resistant tablets.

Basic physical and chemical properties: coated round biconvex tablets, from light-yellow to greenish-yellow or yellow-orange color. Two layers are visible on the cross-section.

Pharmacotherapeutic group. Drugs for constipation. Contact laxatives. Bisacodyl
ATC code A06A B02.

Pharmacological properties.

Pharmacodynamic properties.

Bisacodyl has a laxative effect that is manifested by the defecation softening or rarefying. The mechanism of laxative action is caused by an increased water penetration into the intestinal cavity and a decrease in its absorption, as well as by an acceleration of intestinal motility.

An important place in the mechanism of action has the splitting of bisacodyl in the alkaline contents of the intestine, which leads to the formation of substances that irritate the receptors of the mucous membrane. This leads to stimulation of intestinal peristalsis.

Pharmacokinetic properties.

Intestinal and bacterial enzymes rapidly convert bisacodyl into its active metabolite. Only 5 % of the oral dose is absorbed into the systemic blood, transformed in the liver and excreted in the urine, bilis in the form of an inactive metabolite (glucuronide).

Clinical particulars.

Therapeutic indications.

Short-term symptomatic treatment of intestinal obstruction.

Preparation of the intestine for diagnostic testing, before surgery (under the care of a physician).

Clinical need for relief of defecation with hemorrhoid, anal fistulas and fissures.

Contraindications.

- Increased sensitivity to bisacodyl or any other drug components;
- acute proctitis, acute hemorrhoid, spastic constipation, intestinal obstruction, constricted hernia;
- gastrointestinal bleeding, uterine bleeding;
- acute abdominal syndrome, including appendicitis, other acute inflammatory enteropathies, peritonitis;
- severe abdominal pain accompanied by nausea and vomiting (these symptoms may be manifestations of the aforementioned severe conditions);
- Crohn's disease, nonspecific ulcerative colitis;
- severe dehydration.

Interaction with other medicinal products and other forms of interaction.

It is not recommended to use the drug simultaneously with *H₂-blockers*, *dairy products* and *antacids* (within 1 hour), since there is a risk of rapid dissolution of the outer coat of the tablet and, as a result, irritation of the gastric mucosa and duodenum, impaired bisacodyl efficacy.

Do not consume alkaline foods when taking the drug and during 1 hour before and after taking.

The laxative action of bisacodyl may cause potassium deficiency, so caution should be exercised when using the following drugs with bisacodyl: *diuretics, beta-adrenomimetics, corticosteroids (mineralocorticoids and glucocorticoids), amphotericin B, tetracosactide*, or agents whose toxicity increases with a lack of potassium in the body (for example, *cardiac glycosides*). *Astemizole, terfenadine, erythromycin, amiodarone, sotalol* and *quinidine agents* are not recommended to combine with bisacodyl.

When used with foxglove drugs (*digitalis glycosides*), the risk of hypokalemia and digitalis intoxication increases.

Special warnings and precautions for use.

When using Bisacodyl-Darnitsa, it should be remembered that the latter is an enteric-coated tablet, for this reason it cannot be divided and chewed.

The medicinal product cannot be washed down with alkaline mineral water, used for an hour with milk, antacids or H₂-blockers.

Use with caution in patients with liver and kidney diseases.

It is contraindicated in case of abdominal pain of unknown origin accompanied by nausea and vomiting.

Like all laxatives, bisacodyl should not be taken daily for more than 5 days without examining the causes of constipation.

Prolonged use of high doses may lead to electrolyte imbalance and hypokalemia.

Fluid loss in the gastrointestinal tract may lead to dehydration, symptoms of which may include thirst and oliguria. In patients suffering from fluid loss and for whom dehydration may be harmful (e.g., patients with renal failure, elderly patients), bisacodyl should be discontinued; resumption of use may be possible only under control.

Patients may experience hematochezia (blood in the feces), which is mild and resolves spontaneously.

Cases of dizziness and/or fainting have been reported in patients using bisacodyl. The available data on these cases suggest that these adverse reactions are related to irregular defecation (or difficult defecation) or a vascular-nervous response to abdominal pain, due to constipation and not necessarily due to bisacodyl use.

There have been isolated reports of abdominal pain and bloody diarrhea following bisacodyl administration. Some cases have been associated with ischemia of the colon mucosa.

Bisacodyl should not be taken in children under 10 years of age without medical advice.

In the elderly due to the frequent use of the drug, asthenia, orthostatic hypotension, impaired coordination of movements may occur.

Lack of stimulation of the act of defecation by the drug may indicate an organic cause of constipation.

Laxatives do not help with weight loss.

Together with the use of bisacodyl, it is recommended to follow a certain diet containing a lot of fiber: wholemeal bread, beans and other legumes (if tolerated), fruits and vegetables. It is also necessary to drink enough fluids a day, move more.

Important information about excipients.

The drug contains lactose, therefore, patients with rare hereditary galactose intolerance, lactase deficiency Lapp or glucose-galactose malabsorption should not use the drug.

Fertility, pregnancy and lactation.

The use of the drug during pregnancy and lactation is not recommended because of the lack of safety data for this group of patients.

Effects on ability to drive and use machines.

Patients should be warned that colic may result in dizziness and/or fainting. During treatment, care should be taken when driving vehicles or other mechanisms, and in case of dizziness, refrain from potentially dangerous activities requiring increased concentration of attention and speed of psychomotor reactions.

Posology and method of administration.

For effective defecation in the morning, the preparation should be taken orally before going to bed, regardless of food intake. The tablet should be swallowed without chewing, washed down with a full glass of water.

For a short-term treatment of intestinal obstruction, relief of defecation with hemorrhoid, anal fistulas and fissures:

adults and children over 10 years old: 1-2 tablets (5-10 mg) 1 time per day;

children from 4 to 10 years old: 1 tablet (5 mg) 1 time per day.

For preparation for diagnostic procedures and before operational intervention (under the care of a physician):

adults and children over 10 years old: 2-4 tablets (10-20 mg) once in the evening;

children from 4 to 10 years old: 1 tablet (5 mg) in the evening.

It is not recommended to use the preparation for more than 7 days; daily use of the preparation is not advisable.

Children.

For children under 4 years old, the medicinal product should not be administered.

For children from 4 to 10 years old, the medicinal product should be administered only by doctor's prescription.

Overdose.

Symptoms. The use of high doses can cause diarrhea, abdominal spasms, electrolyte imbalance (including symptoms of hypokalemia and functional atony of the segmented intestine). Chronic overdose can lead to chronic diarrhea, abdominal pain, hypokalemia, secondary hyperaldosteronism, kidney stone disease. There are cases of damage to the renal tubules, metabolic alkalosis and muscle weakness due to hypokalemia. Cases of renal tubular damage, metabolic alkalosis, and muscle weakness through hypokalemia due to chronic laxative abuse have been described.

Treatment. Discard the medicinal product and visit a doctor. It is necessary to rinse the stomach or induce vomiting. Recommended correction of water-electrolyte imbalance (especially important for elderly patients and children), use of symptomatic drugs, and in some cases, antispasmodic agents.

Undesirable effects.

Gastrointestinal disorders: abdominal discomfort, spastic abdominal pain, flatulence, nausea, vomiting, diarrhea, feeling thirsty, dry mouth, colic may occur, rectal irritation, hematochezia (blood in stool), long-term use may cause bowel atony, colonic melanosis, colitis.

Metabolism and nutrition disorders: disruption of the water-electrolyte balance (metabolic acidosis / alkalosis, hypokalemia, hypocalcemia), especially in the elderly, dehydration (as a consequence of dehydration may cause muscle weakness, seizures, arterial hypotension).

Nervous system disorders: dizziness, weakness, loss of coordination of movements, orthostatic hypotension, periodic cramps of the calf muscles (crunches), in severe cases - vasospasm. Dizziness and fainting following the use of bisacodyl, resulting from vasovagal responses (e.g., to colic, defecation).

Immune system disorders: anaphylactic reactions, hypersensitivity reactions, including rash, pruritus, angioedema.

Reported suspected adverse reactions.

Reporting suspected adverse reactions after registration of a medicinal product is an important procedure. This allows for continued monitoring of the benefit/risk ratio for the respective drug. Healthcare providers should be informed of any suspected adverse reactions through the national alert system.

Shelf life. 2 years.

Special precautions for storage.

Store in the original package at temperature not above 25 °C.

Keep out of reach of children.

Nature and contents of container.

10 tablets per a blister; 3 blisters per a pack.

Category of release.

Non-prescription medicine.

Manufacturer.

PrJSC “Pharmaceutical firm “Darnitsa”.

The manufacturer's location and address of the place of business.

13, Boryspilska Street, Kyiv, 02093, Ukraine.

Date of revision of the text.

14.11.2019