



יוני 2024

רופא/ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכון הבא בעלון לרופא של התכשיר:

LAXADIN FILM COATED TABLETS לקסעדין טבליות מצופות

Contains: Bisacodyl 5mg

התוויה כפי שאושרה בתעודת הרישום:

All types of constipation in ambulatory and bedridden in patients over the age of 6 years.  
Preparation of patients for abdominal radiography and proctoscopy.

### עדכונים בעלון לרופא

ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום):

#### 5.1 Pharmacodynamic properties

ATC code: A06AB02

Bisacodyl is a locally acting laxative from the diphenylmethane derivatives group having a dual action. As a contact laxative, for which also antiresorptive hydragogue effects have been described, bisacodyl stimulates after hydrolysis in the large intestine, the mucosa of both the large intestine and of the rectum. Stimulation of the mucosa of the large intestine results in colonic peristalsis with promotion of accumulation of water, and consequently electrolytes, in the colonic lumen. This results in a stimulation of defecation, reduction of transit time and softening of the stool. **Bisacodyl showed improvements in constipation-related symptoms like straining, stool consistency, abdominal discomfort and bloating compared with placebo, based on patient self- assessment questionnaire. Normalization of evacuatory function by bisacodyl treatment was accompanied by a relative normalization of the microflora.**

**The results of two-phase IV clinical trials with a total of 29 patients treated by low dose (5mg) of bisacodyl indicate that the transit through the colon, assessed through MRI, is promoted by stimulating propulsive colon motor activity with bisacodyl. In addition, repeated doses of bisacodyl 5mg during three consecutive days showed an increased in the water content in the**



gut. These trials demonstrated that there was no change in the underlying physiology which showed to return to baseline values 24 hours after ceasing treatment with bisacodyl.

Stimulation of the rectum causes increased motility and a feeling of rectal fullness. The rectal effect may help to restore the “call to stool” although its clinical relevance remains to be established.

As a laxative that acts on the colon, bisacodyl specifically stimulates the **physiological** natural evacuation process in the lower region of the gastrointestinal tract.

**Because its main effect is on distal part of the gut**, bisacodyl is ineffective in altering the digestion or absorption of calories essential nutrients in the small intestine.

העלון לצרכן והעלון לרופא נשלחו לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

, וניתן לקבלם מודפסים ע"י פניה לחברת טבע. <https://israeldrugs.health.gov.il>