"פורמט עלון זה נקבע ע"י משרד הבריאות ותוכנו נבדק ואושר". עלוןמאושר: ספטמבר 2011
"This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved." Date of approval: September 2011.

LAXATIVE COMPOUND

TABLETS

Composition

Each tablet contains:

Active Ingredients

Phenolphthalein	32.0 mg
Powdered Aloes	6.0 mg
Aloin	4.5 mg
Pulv. Ipecacuanhae	4.0 mg
Extr. Belladonnae sicc.	2.7 mg

Other Ingredients

Microcrystalline cellulose, lactose, magnesium stearate, colloidal silicon dioxide, sodium starch glycolate, iron oxide black, iron oxide red, hydroxypropyl methyl cellulose, polyethylene glycol 4000.

Lactose content: 28.75 mg per tablet.
Sodium content: 0.042-0.063 mg per tablet.

Mechanism of Action

Laxative Compound is a laxative containing two peristaltogenics, aloin and phenolphthalein, which act by initiating contractions of the colon. These contractions are reinforced by ipecacuanha. Belladonna is incorporated to prevent possible griping after-effects and pelvic congestion which may be caused by aloin.

Indications

Constipation.

Contraindications

Hypersensitivity to any ingredient of the preparation.
Pregnancy and breastfeeding.
Children under 12 years old.
Acute surgical abdomen.
Not to be taken in the presence of nausea, vomiting, abdominal pain or other symptoms of appendicitis; fecal impaction, intestinal obstruction, undiagnosed rectal bleeding, inflammatory colon diseases (e.g. Crohn's disease, ulcerative colitis), and severe dehydration state with water and electrolyte depletion.
.
Obstructive uropathy (e.g. bladder neck obstruction due to prostatic hypertrophy).

Warnings

If laxatives are needed every day the cause of the constipation should be investigated. Long-term use of laxatives should be avoided.
If stimulant laxatives are taken for longer than a brief period of treatment, this may lead to impaired function of the intestine and dependence on laxatives, and also to electrolyte imbalance.
Patients with kidney disorders should be aware of possible electrolyte imbalance.

If symptoms worsen or do not improve after 7 days, contact a doctor.

Abuse of Laxatives
Typical symptoms of Laxative abuse include abdominal pain, weakness, fatigue, thirst, vomiting, edema, bone pain (due to osteomalacia), fluid and electrolyte imbalance, hypoalbuminemia (due to protein-losing gastroenteropathy), and syndromes that mimic colitis. If the bowel has not been permanently damaged, it may require several months to retain the bowel without the assistance of laxatives.

Belladonna alkaloids may produce a delay in gastric emptying (antral stasis) which would complicate the management of gastric ulcer.Theoretically, with overdosage, a curare-like action may occur.

In the presence of a high environmental temperature, heat prostration can occur with belladonna alkaloids (fever and heatstroke due to decreased sweating). Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.

Use in Pregnancy
Safety of use in pregnancy has not been established. Therefore this drug should not be used during pegnancy.

Use in Breastfeeding
Phenolphthalein appears in breast milk. Use during breastfeeding is not recommended.

Use in Pediatrics
Not to be used in children under 12 years of age.

Adverse Reactions

Abdominal colic and flatulence may occur.
Skin rashes or eruptions may appear in individuals sensitive to phenolphthalein.
Cardiac distress has occurred with phenolphthalein use.
Respiratory distress has occurred with the use of phenolphthalein.

Precautions

Patients should be advised to drink liberally when using laxatives to aid stool softening.

Because of enterohepatic circulation of phenolphthalein, the laxative effects of this preparation may continue for several days.

If a skin rash or any other hypersensitivity reaction occurs, treatment should be discontinued.

Because of the presence of belladonna, even in a small quantity, caution should be exercised in patients with glaucoma, pyloric stenosis, obstructive uropathy, and in conditions characterized by tachycardia.

Because of the phenolphthalein and anthraquinone components, this preparation may impart a pink to reddish color to alkaline urine. Patients should be warned accordingly.

Prolonged use of laxatives may cause dependence for bowel function.

Gastric ulcer may produce a delay in gastric emptying time and may complicate therapy (antral stasis), due to the belladonna content.

Caution should be exercised when this medicine is administered to patients with hyperthyroidism, since belladonna may increase the tachycardia caused by this disorder.

Drug Interactions

Laxative-induced diarrhea may interfere with the full absorption of many drugs. It would therefore be prudent to ensure an adequate interval of time (at least 2 hours), between the ingestion of laxatives and other drugs (including antacids).In the case of oral contraceptives, it is recommended to use additional precautionary measures.

Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of cardiac glycosides and interacts with antiarrhythmic medicinal products, with medicinal products, which induce reversion to sinus rhythm (e.g. quinidine) and with medicinal products inducing QT-prolongation. Concomitant use with other medicinal products inducing hypokalaemia (e.g. diuretics, corticosteroids and liquorice root) may enhance electrolyte imbalance.

Diagnostic Interference

Phenolphthalein and anthraquinones may interfere with Acetest and Ketostix qualitative tests for ketones in urine, by producing a pink to reddish color in alkaline urine.

Dosage and Administration

1-3 tablets at bedtime.

Storage

Store in a dry place below 25°C.

Registration Number

054.58.21072.00.

Manufacturer

Teva Pharmaceutical Industries Ltd
P.O.Box 3190, Petach Tikva.