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LAXADIN®

TABLETS

Composition

Each tablet contains:

Active Ingredient

Bisacodyl 5 mg

Other Ingredients

Lactose monohydrate, microcrystalline cellulose, methacrylic acid copolymer dispersion, talc, formaldehyde- casein (Esma Spreng), starch, gelatin, povidone, magnesium stearate, triethyl citrate, polyethylene glycol 4000, simethicone emulsion.

Lactose content: 40 mg per tablet.

Mechanism of Action

Bisacodyl is a contact laxative which directly stimulates the nerve endings in the colonic mucosa, where it induces reflex peristalsis.

Bisacodyl is virtually not absorbed from the intestine and does not stimulate the uterus. Bisacodyl appears in breast milk in trace amounts.

Lowered intestinal tone does not hinder the action of Laxadin, hence its usefulness in bed-ridden patients with atonic constipation.

Indications

All types of constipation in ambulatory and bed-ridden patients over the age of 6 years.

Preparation of patients for abdominal radiography and proctoscopy.

Contraindications

Known hypersensitivity to any ingredient of the preparation.

Acute surgical abdomen.

Patients with ileus, intestinal obstruction, acute abdominal conditions including appendicitis, acute inflammatory bowel diseases, and severe abdominal pain associated with nausea and vomiting which may be indicative of the aforementioned severe conditions

Severe dehydration.

Undiagnosed rectal bleeding.

Warnings

In preparation for diagnostic procedures, the use of bisacodyl must be under medical supervision

As with all laxatives, this product should not be taken on a continuous daily basis for more than five days without investigating the cause of constipation.

Frequent or prolonged use may cause dependence on laxatives and electrolyte imbalance and hypokalemia, and may precipitate the onset of rebound constipation Electrolyte imbalance may manifest itself as confusion, irregular heart beats, unusual tiredness or weakness, or muscle cramps.

Intestinal loss of fluids can promote dehydration. Symptoms may include thirst and oliguria. In patients suffering from fluid loss where dehydration may be harmful (e.g. renal insufficiency, elderly patients) bisacodyl should be discontinued and only be restarted under medical supervision.

Patients may experience haematochezia (blood in stool) that is generally mild and self-limiting.

Dizziness and/or syncope have been reported in patients who have taken bisacodyl The details available for these cases suggest that the events would be consistent with defaecation syncope (or syncope attributable to straining at stool), or with a vasovagal response to abdominal pain related to the constipation, and not necessarily to the administration of bisacodyl itself.

There have been isolated reports of abdominal pain and bloody diarrhoea occurring after taking bisacodyl. Some cases have been shown to be associated with colonic mucosal ischemia.

This product contains lactose (40 mg) in each tablet. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Use in Pregnancy

There are no adequate and well-controlled studies in pregnant women. Long experience has shown no evidence of undesirable or damaging effects during pregnancy. Nevertheless, as with all medicines, bisacodyl should not be taken in pregnancy, especially the first trimester 1 unless the expected benefit is thought to outweigh any possible risk to the foetus and on medical advice.
No studies on the effect on human fertility have been conducted.

Use in Breastfeeding

Although neither the active ingredient of Bisacodyl tablets (BHPM or bis-(p-hydroxyphenyl)-pyridyl-2-methane) nor its glucuronides are not known to be excreted in breast milk, its use during breast feeding is not recommended. If bisacodyl is used in nursing mothers, infants should be observed for the production of loose stools.

Use in Pediatrics

Not to be used in children under 6 years of age

Adverse Reactions

The most commonly reported adverse reactions during treatment are abdominal pain and diarrhoea..
Adverse events have been ranked under headings of frequency using the following convention: Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, <1/100); rare (≥ 1/10000, <1/1000); very rare (<1/10000).

Immune system disorders
Rare: anaphylactic reactions, angioedema, hypersensitivity.

Metabolism and nutrition disorders
Rare: dehydration.

Nervous system disorders
Uncommon: dizziness.
Rare: Syncope.

Dizziness and syncope occurring after taking bisacodyl appear to be consistent with a vasovagal response (e.g. to abdominal spasm, defecation).

Gastrointestinal disorders
Uncommon: haematochezia (blood in stool), vomiting, abdominal discomfort, anorectal discomfort.
Common: abdominal cramps, abdominal pain, diarrhea and nausea.
Rare: colitis.

Precautions

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

Drug Interactions
N.B: The concomitant use of antacids and milk products may reduce the resistance of the coating of the tablets and result in dyspepsia and gastric irritation.

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. In the case of oral contraceptives, it is recommended to use additional precautionary measures.

The concomitant use of diuretics or adrenocorticosteroids may increase the risk of electrolyte imbalance if excessive doses of biscaodyl are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides

Because of the coating, Laxadin should not be taken within 1 hour of antacid medication.

Effects on ability to drive and use machines
No studies on the effects of bisacodyl on the ability to drive and use machines have been performed. However, patients should be advised that due to a vasovagal response (e.g. to abdominal spasm) they may experience dizziness and / or syncope. If patients experience abdominal spasm they should avoid potentially hazardous tasks such as driving or operating machinery

Dosage and Administration

The tablets should not be chewed or crushed, but swallowed whole.

Adults
1-3 tablets at bedtime.

Children 6 Years of Age and Over
1 tablet or alternatively 0.3 mg/kg/body weight at bedtime.

Overdosage

Symptoms
If high doses are taken watery stools (diarrhoea), abdominal cramps and a clinically significant loss of fluid, potassium and other electrolytes can occur. This may also lead to increased sensitivity to cardiac glycosides.
Laxatives when taken in chronic overdose may cause chronic diarrhoea, abdominal pain, hypokalaemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis and muscle weakness secondary to hypokalaemia have also been described in association with chronic laxative abuse.

Treatment

After ingestion of this product, absorption can be minimised or prevented by inducing vomiting or gastric lavage. Replacement of fluids and correction of electrolyte imbalance may be required. This is especially important in the elderly and the young. Administration of antispasmodics may be of value.

Storage

Store in a dry place below 25°C.

Presentation

30, 50 tablets.

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Manufacturer

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