

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Bisacodyl 5 mg Gastro-resistant Tablets

Biolax 18 years plus 5 mg Gastro-resistant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Bisacodyl 5 mg.

Excipient(s) with known effect

Also contains 41.1 mg of lactose and 36.0 mg of sucrose per tablet.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablets

Yellow sugar-coated tablet with gastro-resistant coating

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the short-term relief of occasional constipation.

4.2 Posology and method of administration

Posology:

Adults: 1 to 2 coated tablets (5-10 mg) daily before bedtime.

Should not be used in children or adolescents under the age of 18 years

It is recommended to start with the lowest dose. The dose may be adjusted up to the maximum recommended dose to produce regular stools. The maximum daily dose should not be exceeded.

In the management of constipation, once regularity has been restarted dosage should be reduced and can usually be stopped.

It is recommended to take the coated tablets at night to have a bowel movement the following morning.

They should be swallowed whole with an adequate amount of fluid.

The coated tablets should not be taken together with products which reduce the acidity of the upper gastrointestinal tract, such as milk, antacids or proton pump inhibitors, in order not to prematurely dissolve the enteric coating.

No specific information on the use of this product in the elderly is available. Clinical trials have included patients over 65 years and no adverse reactions specific to this age group have been reported.

Method of administration

For oral use.

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

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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

Severe dehydration.

4.4 Special warnings and precautions for use

Should not be used in children or adolescents under the age of 18 years.

As with all laxatives, Bisacodyl should not be taken on a continuous daily basis for more than 5 days without investigating the cause of constipation.

Long-term everyday use of stimulant laxatives may harm the intestinal function and should be avoided. If laxatives are needed every day the cause of the constipation should be investigated. This product should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk forming agents.

Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.

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.

Stimulant laxatives (including bisacodyl) do not help with weight loss (see section 5.1).

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

If the symptoms worsen during the use of the medicinal product, a doctor or pharmacist should be consulted.

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 defecation 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 ischaemia.

Bisacodyl contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Bisacodyl contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The leaflet will state:

“Before you take this medicine” section

Does this help with weight loss?

Stimulant laxatives (including bisacodyl) do not help with weight loss. They do not reduce the absorption of calories or nutrients. They can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

Overuse of laxatives may damage your health by:

- Causing disturbances of electrolyte and mineral balances. Sodium, potassium, magnesium, and phosphorous are electrolytes and minerals that are present in very specific amounts necessary for proper functioning of the nerves and muscles, including those of the colon and heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs.
- Severe dehydration may cause tremors, weakness, blurry vision, fainting, kidney damage, and, in extreme cases, death. Dehydration often requires medical treatment.
- Overuse of laxatives must be avoided as it may harm the intestinal function.

The label will state:

Front of pack:

- Does not help with weight loss.
- Overuse can be harmful.

4.5 Interaction with other medicinal products and other forms of interaction

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.

The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of Bisacodyl are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

The concomitant use of other laxatives may enhance the gastrointestinal side effects of Bisacodyl.

4.6 Fertility, pregnancy and lactation

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.

Breast-feeding

Clinical data show that neither the active moiety of Bisacodyl (BHPM or bis-(p-hydroxyphenyl)-pyridyl-2-methane) nor its glucuronides are excreted into the milk of healthy lactating females

Nevertheless, as with all medicines, Bisacodyl should not be taken in pregnancy, especially the first trimester, and during breast feeding unless the expected benefit is thought to outweigh any possible risk and only on medical advice.

Fertility

No studies on the effect on human fertility have been conducted.

4.7 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.

4.8 Undesirable effects

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 ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$).

Immune system disorders:

Rare: Hypersensitivity, anaphylactic reactions, angioedema

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, defaecation).

Gastrointestinal disorders

Common: Abdominal pain, abdominal cramps, nausea and diarrhoea.

Uncommon: Vomiting, haematochezia (blood in stool), abdominal discomfort, anorectal discomfort.

Rare: Colitis including ischaemic colitis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit / risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms:

If high doses are taken watery stools (diarrhoea), abdominal cramps and a clinically significant loss of fluid, potassium and other electrolytes can occur.

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.

Therapy:

After ingestion of oral forms of Bisacodyl, 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 some value.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Laxatives; ATC code: A06AB02

Bisacodyl is a locally acting stimulant 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. 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 natural evacuation process in the lower region of the gastrointestinal tract. Therefore, bisacodyl is ineffective in altering the digestion or absorption of calories or essential nutrients in the small intestine.

5.2 Pharmacokinetic properties

Following either oral or rectal administration, bisacodyl is rapidly hydrolyzed to the active principle bis-(p-hydroxyphenyl)-pyridyl-2-methane (BHPM), mainly by esterases of the enteric mucosa.

Administration as an enteric coated tablet was found to result in maximum BHPM plasma concentrations between 4 – 10 hours post administration whereas the laxative effect occurred between 6 – 12 hours post administration. In contrast, following the administration as a suppository, the laxative effect occurred on average approximately 20 minutes post administration; in some cases it occurred 45 minutes after administration. The maximum BHPM-plasma concentrations were achieved 0.5 – 3 hours following the administration as a suppository. Hence, the laxative effect of bisacodyl does not correlate with the plasma level of BHPM. Instead, BHPM acts locally in the lower part of the intestine and there is no relationship between the laxative effect and plasma levels of the active moiety. For this

reason, bisacodyl coated tablets are formulated to be resistant to gastric and small intestinal juice. This results in a main release of the drug in the colon, which is the desired site of action.

After oral and rectal administration, only small amounts of the drug are absorbed and are almost completely conjugated in the intestinal wall and the liver to form the inactive BHPM glucuronide. The plasma elimination half-life of BHPM glucuronide was estimated to be approximately 16.5 hours. Following the administration of bisacodyl coated tablets, an average of 51.8% of the dose was recovered in the faeces as free BHPM and an average of 10.5% of the dose was recovered in the urine as BHPM glucuronide. Following the administration as a suppository, an average of 3.1% of the dose was recovered as BHPM glucuronide in the urine. Stool contained large amounts of BHPM (90% of the total excretion) in addition to small amounts of unchanged bisacodyl.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose

Maize starch

Magnesium stearate

Pregelatinised maize starch

Cellulose acetate phthalate

Diethylphthalate

Talc

Sucrose

Povidone

Titanium dioxide

Quinoline yellow (E104)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package

6.5 Nature and contents of container

Strips of 250 micron PVC glass-clear/bluish rigid PVC (Pharmaceutical grade) 20 micron hard-tempered aluminium foil coated on the dull side with 6-7 gsm heat seal lacquer and printed on the bright side.

Pack sizes: 10 and 20

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited

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3rd Floor, 1060 Nicosia

Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0139

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07/12/2022