

PACKAGE INSERT TEMPLATE FOR BISACODYL TABLET & SUPPOSITORIES

Brand or Product Name

[Product name] Tablet 5mg

[Product name] Suppositories 5mg & 10mg

Name and Strength of Active Substance(s)

Bisacodyl ...mg

Product Description

[Visual description of the appearance of the product (eg colour, markings etc)]

eg White, circular flat beveled edge tablets marked '100' on one side

White torpedo shaped suppositories with smooth surface

Pharmacodynamics

Bisacodyl is a locally acting laxative from the diphenylmethane derivatives group. As a contact laxative, for which also antiresorptive hydragogue effects have been described, bisacodyl stimulates, after hydrolysis in the large intestine, peristalsis of the colon and promotes accumulation of water and consequently electrolytes in the colonic lumen. This results in a stimulation of defecation, reduction of transit time, and a softening of the stool.

Pharmacokinetics

Absorption

Absorption from the gastrointestinal tract is minimal with enteric-coated tablets or suppositories

Oral, tablet: negligible

Rectal, suppository: negligible

Administration as an enteric coated tablet was found to result in maximum bis(p-hydroxyphenyl)pyridyl-2-methane (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.

Updated January 2012

Metabolism

Bisacodyl is hydrolyzed to bis(p-hydroxyphenyl)pyridyl-2-methane (BHPM), which is responsible for its laxative effects

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.

Almost completely conjugated in the intestinal wall and the liver to form the inactive BHPM glucuronide.

Excretion

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.

Indication

For use in patients suffering from constipation

For preparation of diagnostic procedures, in pre- and postoperative treatment and in conditions, which require defecation to be facilitated (used under medical supervision)

Recommended Dosage

* Its action is mainly in the large intestine and it is usually effective within 6 to 12 hours after oral doses, within 15 to 60 minutes after rectal use by suppository

Tablets

*Bisacodyl tablets should be swallowed whole, not chewed or crushed and should not be taken within 1 hour of milk or antacids.

Unless otherwise prescribed by the physician, the following dosages are recommended:

Updated January 2012

For constipation

Adults and children over 10 years: 5 - 10 mg

Children 4 - 10 years: 5 mg

Children under 4 years: paediatric suppositories are recommended

Children aged 10 years or younger with chronic or persistent constipation should only be treated under the guidance of a physician.

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 reducing the acidity of the upper gastrointestinal tract, such as milk, antacids or proton pump inhibitors, in order to dissolve the enteric coating.

Suppositories

*Suppositories are usually effective in about 20 minutes (range 10-30 minutes).

*Retain about 15 to 20 minutes

*They should be unwrapped and inserted into the rectum pointed end first.

Unless otherwise prescribed by the physician, the following dosages are recommended:

For constipation

Adults and children over 10 years: 10 mg

Children under 10 years: 5 mg

Children aged 10 years or younger with chronic or persistent constipation should only be treated under the guidance of a physician.

Updated January 2012

For preparation for diagnostic procedures and preoperatively

For preparation of diagnostic procedures, in pre- and postoperative treatment and in medical conditions which require defecation to be facilitated, bisacodyl should be used under medical supervision.

In order to achieve complete evacuation of the intestine the bisacodyl dosage recommended for adults is two to four coated tablets the night before the examination, followed by one suppository in the morning of the examination. For children 4 years of age and over, one coated tablet in the evening and one paediatric suppository on the following morning is recommended.

Mode of Administration

Oral

Rectal

Contraindications

Bisacodyl is contraindicated in patients with ileus, gastroenteritis, intestinal obstruction, acute surgical abdominal conditions including appendicitis, acute inflammatory bowel diseases, and severe abdominal pain associated with nausea and vomiting which may be indicative of more severe conditions. Bisacodyl is also contraindicated in severe dehydration and in patients with known hypersensitivity to bisacodyl or any other component of the product.

In case of rare hereditary conditions that may be incompatible with an excipient of the product, the use of the product is contraindicated.

Warnings and Precautions

As with all laxatives, Bisacodyl should not be taken on a continuous daily basis or for extended periods without investigating the cause of constipation.

Use for more than 7 days is not recommended

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.

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

Updated January 2012

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.

Children should not take Bisacodyl without medical advice.

The use of suppositories may lead to painful sensations and local irritation, especially in anal fissure, ulcerated haemorrhoids and ulcerative proctitis hence should preferably be avoided in such patients

Effects of Food:

Do not take within 1 hour of milk ingestion

Ingestion of milk within one hour of administration of bisacodyl tablets may cause rapid dissolution of the enteric coating resulting in gastric or duodenal irritation

Patients with rare hereditary conditions of galactose intolerance, e.g. galactosaemia, should not take this medicine (if applicable).

Patients with the rare hereditary condition of fructose intolerance should not take this medicine (if applicable).

Care should also be taken in patients with inflammatory bowel disease.

It should not be used in patients with severe dehydration.

Interactions with Other Medicaments

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*.

Calcium

Interaction Effect: decreased effectiveness of bisacodyl

Cimetidine

Interaction Effect: decreased effectiveness of bisacodyl

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Milk

Interaction Effect: gastric or duodenal irritation

Administration of milk within one hour of bisacodyl tablets may cause the enteric coating to dissolve too rapidly, resulting in gastric or duodenal irritation

Statement on Usage During Pregnancy and Lactation

Pregnancy

There is no data on the use of bisacodyl in pregnant women. The effects, if any, on the developing fetus are unknown. Bisacodyl should only be used during pregnancy if the maternal condition justifies the potential risk to the fetus.

Lactation

No reports describing the use of bisacodyl during human lactation are available and the effects on the nursing infant from exposure to the drug in milk are unknown. It is not known if bisacodyl affects the quantity and composition of breastmilk. Bisacodyl is thought to be minimally absorbed into systemic circulation when administered orally or rectally. Until more data are available, use caution when considering bisacodyl in lactating women.

Adverse Effects / Undesirable Effects

Immune system disorders

Anaphylactic reactions, angioedema, hypersensitivity

Metabolism and nutrition disorders

Dehydration

Gastrointestinal disorders

Colitis, abdominal cramps, abdominal pain, diarrhoea, vomiting, nausea, abdominal discomfort, anorectal discomfort

There is also the possibility of developing an atonic non-functioning colon.

Haematochezia (blood in the stool) may be seen but is usually mild and self-limiting; more severe bloody diarrhoea may be associated with colonic mucosal ischaemia.

When given rectally, bisacodyl sometimes causes irritation and may cause proctitis or sloughing of the epithelium.

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Overdose and Treatment

Symptoms

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

Bisacodyl, as with other 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 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 value.

Storage Conditions

[eg Store below.... °C]

Dosage Forms and Packaging Available

[Packaging type & pack size]

Name and Address of Manufacturer

[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder

[Name & full address of marketing authorization holder]

Date of Revision of Package Insert

[day/month/year]

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