1.6 product information

1.6.1 Prescribing information (Summary of product characteristics)

1. Name of the medicinal product

Bisacodyl 5mg Tablets

2. Qualitative and quantitative composition

Bisacodyl BP 5.00mg

3. Pharmaceutical form

Enteric coated tablets

4. Clinical particulars

4.1 Therapeutic indications

Bisacodyl Tablets are stimulant laxatives used for the treatment of constipation and for bowel evacuation before investigational procedures or surgery. Constipation can often be resolved without course to laxatives and an adjustment in the diet to increase vegetable fibre and fluid intake may be all that is required. However, the use of laxatives .such as Bisacodyl may be necessary in certain conditions, for example to reduce excessive straining in cardiovascular disease or in patients with hemorrhoids, to reduce the pain of defecation following surgery, or when constipation is due to neurological defects, hormonal changes as in pregnancy, or treatment with certain drugs such as opioid analgesics.

Stimulant laxatives including Bisacodyl should only be used in functional constipation that has not responded to dietary measures and should be withdrawn as soon as possible. Bisacodyl is also used for bowel evacuation before radiological examination, endoscopy, surgery, or childbirth.

4.2 Posology and method of administration

Bisacodyl Tablets are administered by the oral route preferably at bedtime. The tablets should be swallowed whole and should not be taken at the same time as milk or antacids. It is administered at the usual dose of 2 tablets (10 mg) daily, doses of up to 30 mg have been given orally to complete bowel evacuation. Children may be given 1 to 2 tablets (5-10 mg) orally.

4.3 Contraindications

Bisacodyl is contraindicated in 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.

Bisacodyl is also contraindicated in severe dehydration and in patients with known hypersensitivity to bisacodyl or any other component of the product.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.4 Special warnings and precautions for use
As with all laxatives, Bisacodyl should not be taken on a continuous daily basis for more than five days without investigating the cause of constipation.

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

Intestinal loss of fluids may 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 Tablets do not help with weight loss (see section 5.1 Pharmacodynamic properties).

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 ischaemia.

Bisacodyl should not be taken by children under 10 years without medical advice.

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

The tablets should not be crushed or chewed but swallowed whole. Antacids should not be given one hour after taking the tablets.

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 Tablets.

4.6 Fertility, pregnancy and lactation
There are no adequate and well-controlled studies in pregnant women. Long experience has shown no evidence of undesirable or damaging effects during pregnancy.

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.

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 (≥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, defaecation).

Gastrointestinal disorders

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

Common: abdominal cramps, abdominal pain, diarrhoea and nausea

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.

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 value.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Drugs for constipation, Contact laxatives

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. 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

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients
Dicalcium Phosphate

White Corn Starch

Microcrystalline Cellulose pH 101

Povidone K-90 (PVPK-90)

Potassium Sorbate

Purified Talc

Magnesium Stearate

Novomix ENT 04-109005- White

Tartrazine Yellow Lake Colour

Purified water

6.2 Incompatibilities
None known

6.3 Shelf life
3 years

6.4 Special precautions for storage
Store in a dry place, below 30°C.
Protect from light,
Keep all medicines out of reach of children

6.5 Nature and contents of container
Yellow, circular, biconvex Enteric Coated tablets, plain on both sides. Packed in Blister pack of 10 x 10's or 1000's in HDPE container with literature insert**.**

6.6 Special precautions for disposal and other handling
Not applicable.

7. Marketing Authorization Holder and Manufacturing Site Addresses Marketing Authorization Holder:
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8. Marketing authorisation number(s)

Kenya: 3583

9. Date of first authorisation/renewal of the authorisation

Kenya: 2/1/1985

10. Date of revision of the text

April 2019