NEW ZEALAND DATA SHEET

BISACODYL VIATRIS

1. Product Name

Bisacodyl Viatris, 5 mg, enteric coated tablet.

2. Qualitative and Quantitative Composition

Each enteric coated tablet contains 5 mg of bisacodyl.

Excipient with known effect: lactose.

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Yellow round biconvex coated tablets.

4. Clinical Particulars

4.1 Therapeutic indications

For short term relief of constipation.

In preparation for diagnostic procedures, in pre- and postoperative treatment and in conditions whichrequire defecation, the use of Bisacodyl Viatris must be under medical supervision.

4.2 Dose and method of administration

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

Adults and children over 10 years: 1 to 2 coated tablets at night (5 to 10 mg).

Children 4 to 10 years: One coated tablet at night (5 mg).

Notes: Bisacodyl Viatris tablets are coated. The tablets should be taken at night to produce evacuation the following morning. They should be swallowed whole with adequate fluid.

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

4.3 Contraindications

Bisacodyl Viatris should not be used by patients with ileus, 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 Viatris 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 (refer to section 4.4) the use of the product is contraindicated.

4.4 Special warnings and precautions for use

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

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 Viatris should be discontinued and only be restarted under medical supervision.

Stimulant laxatives including Bisacodyl Viatris 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 Viatris. 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 responseto abdominal pain related to the constipation and not necessarily to the administration of Bisacodyl Viatris itself.

One coated tablet contains 17.71 mg lactose, resulting in 35.42 mg lactose per maximum recommended daily dose for treatment of constipation in adults and children over 10 years of age. Patients with rare hereditary conditions of galactose intolerance, e.g. Galactosaemia, should not take this medicine.

One coated tablet contains 1.11 mg sucrose, resulting in 2.22 mg sucrose per maximum recommended daily dose for treatment of constipation in adults and children over 10 years of age. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of Bisacodyl Viatris are taken. Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

Potassium deficiency may occur due to exposure to bisacodyl, so this medicinal product should be taken with caution in patients who are taking other potassium-lowering medicinal products (e.g., diuretics, steroids), or medicinal products which have their toxic effect increasing if the body is lacking in potassium (e.g., cardiac glycosides).

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

The tablets should not be taken with milk and/or products that reduce the acidity of the upper gastrointestinal tract.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate and well-controlled studies in pregnant women. Long experiencehas shown

no evidence of undesirable or damaging effects during pregnancy.

Nevertheless, as with all drugs, Bisacodyl Viatris should be taken during pregnancy only on medical advice.

Breast-feeding

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

This medicinal product may be used during lactation if the expected benefit outweighs the potential risk to the infant.

Nevertheless, as with all drugs, Bisacodyl Viatris should be taken during breastfeeding 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 Viatris 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.

Immune system disorders

Anaphylactic reactions, angioedema, hypersensitivity.

Metabolism and nutrition disorders

Dehydration, hypokalaemia

Nervous system disorders

Dizziness, syncope.

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

Gastrointestinal disorders

Abdominal cramps, abdominal pain, diarrhoea, vomiting, nausea, haematochezia (blood in stool), abdominal discomfort, anorectal discomfort, colitis including ischaemic colitis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/.

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.

Bisacodyl Viatris, 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

Within a short time after ingestion of oral forms of Bisacodyl Viatris, absorption can be minimized or prevented by inducing vomiting. Replacement of fluids and correction of electrolyte imbalance may be required. This is especially important in the elderlyand the young.

Administration of antispasmodics may be of value.

For further advice on management of overdose please contact the National Poisons Information Centre (0800 POISON or 0800 764 766).

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: contact laxatives, ATC code: A06AB

Mechanism of action

Bisacodyl, the active ingredient of Bisacodyl Viatris, is a locally acting laxative from the diphenylmethane derivatives group. It is a contact laxative, for which antiresorptive hydragogue laxative effects have been described. After metabolism by hydrolysis in the large intestine, the active form of bisacodyl stimulates 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 softening of the stool. Bisacodyl showed improvements in constipation-related symptoms like straining, stool consistency, abdominal discomfort and bloating compared with placebo, based on patient self-assessment questionnaire. Normalisation of evacuatory function by bisacodyl treatment was accompanied by a relative normalisation of the microflora.

The results of two-phase IV clinical trials with a total of 29 patients treated by low dose (5 mg) of bisacodyl indicate that the transit through the colon, assessed through MRI, is promoted by stimulating propulsive colon motor activity with bisacodyl. In addition, repeated doses of bisacodyl 5 mg during three consecutive days showed an increased in the water content in the gut. These trials demonstrated that there was no change in the underlying physiology which showed to return to baseline values 24 hours after ceasing treatment with bisacodyl.

As a laxative that acts on the colon, bisacodyl specifically stimulates the natural evacuation process in the lower region of the gastrointestinal tract. Because its main effect is on the distal part of the gut, 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 entericmucosa.

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 data sheet.

6. Pharmaceutical Particulars

6.1 List of excipients

Bisacodyl Viatris enteric coated tablet also contains:

Core:

- Lactose monohydrate
- Microcrystalline cellulose
- Hydroxyl propyl cellulose
- Pregelatinised starch
- Magnesium stearate

Coating:

- Hypromellose
- Triethyl citrate
- Purified talc
- Eudragit L 100
- Eudragit S 100
- Isopropyl alcohol
- Sucrose
- Hypromellose
- Magnesium stearate
- Titanium dioxide
- iron oxide yellow
- Carnauba wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

Store in a safe place out of reach of children.

6.5 Nature and contents of container

PVC/Al or PVC/PVDC Al blister packs of 30, 50, 100, 150, 200.

Not all pack types and sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7. Medicines Schedule

Pharmacy only medicine

8. Sponsor Details

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9. Date of First Approval

15 February 2018

10. Date of Revision of the Text

08 August 2024

Summary table of changes

Section	Summary of new information
4.8	Updated ADR reporting website.
5.1	Addition of information to mechanism of action section.