1 NAME OF THE MEDICINAL PRODUCT

Bisacodyl 10 mg Suppositories

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Bisacodyl BP 10mg

3 PHARMACEUTICAL FORM

Suppository

For Rectal Use

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Bisacodyl is a stimulant laxative used for the short-term relief of occasional constipation.

4.2 Posology and method of administration

Posology

Short-term relief of occasional constipation:
Adults and children over 12 years:
1 suppository (10 mg) for immediate effect.

Children and adolescents under 12 years:
Should not be used in children and adolescents under the age of 12 years.

Method of Administration

For Rectal Use Only
Do not swallow

4.3 Contra-indications

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.

Bisacodyl Suppositories should not be used when anal fissures or ulcerative proctitis with mucosal damage are present.

4.4 Special warnings and precautions for use

Prolonged use may precipitate the onset of an atonic, non-functioning colon.

Laxatives do not help in long-term weight loss.

As with all laxatives, Bisacodyl Suppositories should not be used 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 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 Suppositories 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 Suppositories. 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.

The use of suppositories may lead to painful sensations and local irritation, especially in patients with anal fissures and ulcerative proctitis.

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

4.5 Interaction with other medicinal products 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 are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

4.6 Fertility, pregnancy and lactation

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

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.

Lactation
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 Suppositories 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.

4.7 Effects on ability to drive and use machines

No studies on the effects of Bisacodyl Suppositories 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

Use of the suppositories can occasionally cause rectal irritation, and repeated use may cause proctitis or sloughing of the epithelium. Prolonged use can result in diarrhoea with excessive loss of water and electrolytes, particularly potassium. There is also the possibility of developing an atonic non-functioning colon.

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).

Not known – incidence cannot be estimated from the available data.

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

Metabolism and nutrition disorders
Rare: dehydration.

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

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).

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

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: Contact laxatives
ATC code: A06AB

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

5.2. Pharmacokinetic Properties

The bisacodyl is present in a micronised state, but apart from this, the base will not affect the rate of action of the drug.
The suppositories are usually effective within 15 - 60 minutes.

5.3. Pre-clinical Safety Data

No additional data of relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Witepsol H15

6.2. Incompatibilities

None known

6.3. Shelf-Life

3 years (36 Months) unopened.

6.4. Special Precautions for Storage

Store in a dry place below 25°C and away from direct light.

6.5 Nature and contents of container

The suppositories are sealed in plastic (PVC/PE) cavities within a cardboard carton in pack quantities of 12 (10mg) suppositories.

6.6. Instructions for Use, Handling and Disposal

To remove suppository , tear one from the strip along the perforation then peel it from the container by pulling apart the tabs at the top of the suppository.

8 MARKETING AUTHORISATION HOLDER

Martindale Pharmaceuticals Ltd

Bampton Road,

Romford,

RM3 8UG

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00156/0045

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

06 June 1997

10 DATE OF REVISION OF THE TEXT

02/12/2019