SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Gutbless 5 mg Suppositories.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Suppository contains
Bisacodyl BP …. ….. 5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White to off white color torpedo shaped suppository.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Gutbless is a stimulant laxative used for the chronic or recent onset of constipation.

4.2 Posology and method of administration

Posology

Short-term relief of occasional constipation:
Children 4 – 10 years: 1 suppository (5 mg) daily for immediate effect.
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.
Children aged 10 years or younger with chronic or persistent constipation should only be treated under the guidance of a physician. Bisacodyl should not be used in children aged 4 years or younger.

Instructions for use:
Suppositories are usually effective in about 20 minutes (usual range 10 to 30 minutes). Rarely the laxative effect has been reported 45 minutes after administration. They should be unwrapped and inserted into the rectum pointed end first.
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.

4.3 Contraindications

Gutbless 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.
Gutbless is also contraindicated in severe dehydration and in patients with known hypersensitivity to bisacodyl or any other component of the product.
Gutbless Suppositories should not be used when anal fissures or ulcerative proctitis with mucosal damage are present.

4.4 Special warnings and precautions for use

As with all laxatives, Bisacodyl Suppository should not be used on a continuous daily basis for more than five days 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 Suppository should be discontinued and only be restarted under medical supervision.
Stimulant laxatives including Bisacodyl 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 Suppository. 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 Suppository 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 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 Suppository 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 Suppository.

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
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

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

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. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

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: 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.

The authority/EFDA will review new information on this medicinal product at least every year and this SmPC will be updated as necessary.

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 additional data of relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hard Fat (Witepsol W-45 pastilles).

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in dry place, temperature below 30°C. Do not freeze.
Keep all medicines out of reach of children.

6.5 Nature and contents of container

6 suppositories are packed in PVC/PE strip; such 1 strip is packed along with instruction for medical use in a carton pack.
5 suppositories are packed in PVC/PE strip; such 2 strips are packed along with instruction for medical use in a carton pack.
5 suppositories are packed in PVC/PE strip; such 20 strips are packed along with instruction for medical use in a carton pack.

6.6 Special precautions for disposal <and other handling>

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

Kusum Healthcare Pvt. Ltd.
SP-289(A), RIICO Industrial Area,
Chopanki, Bhiwadi, Dist. Alwar, Rajasthan, India

8. MARKETING AUTHORISATION NUMBER(S)

07736/08528/NMR/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 September 2022

10. DATE OF REVISION OF THE TEXT

08/2023

11. REFERENCES

SmPC published on electronic medicines compendium
https://www.medicines.org.uk/emc#gref

The MHRA published product information
https://products.mhra.gov.uk/

Human medicine European public assessment report
https://www.ema.europa.eu/en/medicines