Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

CONLAX-5 (Bisacodyl Suppositories BP 5 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains 5 mg of Bisacodyl BP
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suppository for rectal administration

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

It is used for the treatment of constipation and for bowel evacuation before investigational procedures or surgery. Its action is mainly in the large intestine and it is usually effective within 15 to 60 min.

4.2 Posology and method of administration

For Constipation:

Adults and children over 10 years: One 10mg Bisacodyl as suppository is given in morning.

Children under 10 years: One 5mg suppository to be inserted in morning

For bowel clearance before surgery, X-rays or other tests:

Adults and children above 10years:1 suppository (10 mg) for immediate effect

Children under 10 years: 1 suppository (5 mg) for immediate effect

4.3 Contraindications

CONLAX-5 suppositories 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.

CONLAX-5 suppositories is also contraindicated in severe dehydration and in patients with known hypersensitivity to Bisacodyl or any other component of the product.

CONLAX-5 Suppositories should not be used when anal fissures or ulcerative proctitis with mucosal damage are present.

4.4 Special warnings and precautions

CONLAX-5 suppositories should not be used for longer time without investigation of the cause of constipation. Prolonged use may lead to the fluid and electrolyte imbalance, excessive loss of potassium can cause 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 (renal insufficiency, elderly patients) Dizziness and / or syncope have been reported in patients who have taken CONLAX-5.

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

CONLAX-5 can cause local irritation. It is generally avoided in patients suffering from anal fissures.

4.5 Interaction with other medicinal products and other form of interactions:

The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of CONLAX-5 are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

4.6 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 nor its glucuronides are excreted into the milk of healthy lactating females.

Nevertheless, as with all medicines, CONLAX-5 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 CONLAX-5 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:

CONLAX-5 Suppositories are suitable for most people, but, like all medicines, they can sometimes cause side effects.

It may sometimes cause rectal irritation and sloughing of epithelium. It may cause abdominal discomfort such as colic or cramps. Prolonged use or over dosage may result in diarrhoea with excessive loss of water and electrolytes, especially potassium; there is also possibility of developing an atonic non-functioning colon. Hypersensitivity reaction including angioedema and anaphylactic reaction are reported rarely.

4.9 Overdose

If high doses are taken watery stools (diarrhoea), abdominal cramps and a clinically significant loss of fluid, potassium and other electrolytes can occur. In case of over dose immediately consult your doctor.

5. PHARMACOLOGICAL PROPERTIES:

5.1Pharmacodynamic properties:

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.

5.2 Pharmacokinetic properties:

There is minimal absorption of bisacodyl from the gastrointestinal tract. Since bisacodyl is stimulant laxative, its action is local rather than systemic thus low systemic absorption of bisacodyl from gastrointestinal tract is useful for its action.

After rectal administration of bisacodyl, it is converted into the active desacetyl metabolite bis(p-hydroxyphenyl)-pyridyl-2-methane by intestinal and bacterial enzymes.

Very small amount of bisacodyl is systemically absorbed and it is excreted in the urine as the glucuronide. Bisacodyl is mainly excreted in the faeces.

5.3 Preclinical safety data

Not available

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Hard Fat Ph.Eur

6.2 Incompatibilities

Not known

6.3 Shelf Life

24 months

6.4 Special precaution for storage

Store in a dry place below 30^0 C protected from light.

6.5 Nature and content of container

CONLAX-5 suppositories are packed in thermo formable polyvinylchloride foil coated with Polyethylene. One strip of 5 suppositories is packed in one mono carton along with pack insert.

7. MARKETING AUTHORIZATION HOLDER

BLISS GVS PHARMA LIMITED

102, Hyde Park, Saki-Vihar road

Andheri (East) Mumbai 400 072

INDIA

8. MARKETING AUTHORIZATION NUMBER

Registration number: 04313/4880/NMR/2017

9. DATE OF FIRST AUTHORIZATION

26.02.20219

10. DATE OF REVISION OF TEXT

July 2023