1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

LAXADOR BISACODYL SUPPOSITORIES 10 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository of LAXADOR BISACODYL SUPPOSITORIES contains 10 mg Bisacodyl.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suppositories.

LAXADOR BISACODYL SUPPOSITORIES is a white torpedo-shaped suppository.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

LAXADOR BISACODYL SUPPOSITORIES is indicated for the treatment of occasional constipation.

4.2. Posology and method of administration

Posology

Unless otherwise prescribed by your doctor, the following dosages are recommended:

Adults and children 12 years and over:

Insert one suppository as a single daily dose.

Method of administration

For rectal administration.

The suppositories should be unwrapped and inserted into the rectum pointed end first.

Bowel movement is generally produced within 15 minutes to one hour.

4.3. Contraindications

LAXADOR BISACODYL SUPPOSITORIES is contraindicated in:

- Patients with hypersensitivity to bisacodyl or to any excipients in LAXADOR BISACODYL SUPPOSITORIES (see section 6.1).
- Ileus, intestinal obstruction, undiagnosed abdominal symptoms or acute surgical abdominal conditions like acute appendicitis, acute inflammatory bowel disease, severe abdominal pain associated with nausea and vomiting which may be indicative of the aforementioned severe conditions and in severe dehydration.
- Presence of anal fissures or ulcerative proctitis with mucosal damage.

4.4. Special warnings and precautions for use

LAXADOR BISACODYL SUPPOSITORIES should not be used in the presence of abdominal pain, nausea or vomiting.

If you have noticed a sudden change in bowel habits that has persisted for a period of greater than

2 weeks, consult a doctor before using the laxative.

Frequent or prolonged use of LAXADOR BISACODYL SUPPOSITORIES may result in

dependence on laxatives and loss of normal bowel function. The use of LAXADOR BISACODYL SUPPOSITORIES beyond 1 week is not recommended except on the advice of a doctor.

If a laxative is needed every day, the cause of constipation should be investigated.

LAXADOR BISACODYL SUPPOSITORIES should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk forming medicines.

Prolonged use may lead to diarrhoea with excessive loss of water and electrolytes and possible atonic non-functioning colon.

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) LAXADOR BISACODYL SUPPOSITORIES should be discontinued and only be restarted under medical supervision.

Stimulant laxatives (including LAXADOR BISACODYL SUPPOSITORIES) do not help with weight loss (see section 5.1).

They do not reduce the absorption of calories or nutrients. They can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

Overuse of laxatives may damage a patient's health by:

- Causing disturbances of electrolyte and mineral balances. Sodium, potassium, magnesium, and phosphorus are electrolytes and minerals that are present in very specific amounts necessary for proper functioning of the nerves and muscles, including those of the colon and heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs.
- Severe dehydration may cause tremors, weakness, blurry vision, fainting, kidney damage, and, in extreme cases, death. Dehydration often requires medical treatment.
- Overuse of laxatives must be avoided as it may harm the intestinal function.

Patients may experience haematochezia (blood in stool) that is generally mild and self-limiting.

If the symptoms worsen during the use of LAXADOR BISACODYL SUPPOSITORIES, a doctor or pharmacist should be consulted.

Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a doctor.

Dizziness and / or syncope have been reported in patients who have taken LAXADOR 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 (see sections 4.7 and 4.8)

There have been reports of abdominal pain and bloody diarrhoea occurring after taking bisacodyl, as contained in LAXADOR BISACODYL SUPPOSITORIES, orally. Some cases have been shown to be associated with colonic mucosal ischaemia.

Administration of suppositories may cause painful sensations and local irritation, care should be taken in patients with rectal fissures or ulcerated haemorrhoids. May cause irritation and repeated use may cause proctitis or sloughing of the epithelium.

Excessive purgation has been reported.

Care should be taken in patients with inflammatory bowel disease.

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 LAXADOR BISACODYL SUPPOSITORIES 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 LAXADOR BISACODYL SUPPOSITORIES.

4.6. Fertility, pregnancy and lactation

The safety of LAXADOR BISACODYL SUPPOSITORIES in pregnancy and lactation has not been established.

Pregnancy

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

Breastfeeding

Not applicable.

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 LAXADOR 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 (see sections 4.4 and 4.8).

4.8. Undesirable effects

a) Tabulated list of adverse reactions

System organ class	Frequent	Less frequent
Immune system disorders		Anaphylactic reactions, angioedema, hypersensitivity (allergic reactions)
Metabolism and nutrition disorders		Dehydration
Nervous system disorders		Dizziness, syncope,
Gastrointestinal disorders	Abdominal cramps, abdominal pain, diarrhoea, nausea	Haematochezia (blood in stool), vomiting, abdominal discomfort, anorectal discomfort, colitis including ischaemic colitis

Description of selected adverse reactions

Dizziness and syncope occurring after taking bisacodyl, as contained in LAXADOR BISACODYL SUPPOSITORIES, appear to be consistent with a vasovagal response (e.g. to abdominal spasm, defaecation) (see sections 4.4 and 4.8).

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 providers are asked to report any suspected adverse reactions to **SAHPRA** via the the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found

on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LAXADOR BISACODYL SUPPOSITORIES.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9. Overdose

Symptoms

If high doses are taken, watery stools (diarrhoea), abdominal cramps and a clinically significant loss of potassium and other electrolytes can occur.

Chronic overdose with LAXADOR BISACODYL SUPPOSITORIES 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

Treatment is symptomatic and supportive.

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

Category and Class: A 11.5 Laxatives

Pharmacotherapeutic group: Contact laxatives, Bisacodyl

ATC code: A06AB02

Mechanism of action

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

Absorption

After rectal administration, clinically insignificant amounts of bisacodyl are absorbed as it is almost completely conjugated in the intestinal wall and the liver to form the inactive BHPM glucuronide.
Following the administration as a suppository, the laxative effect occurred on average approximately between 20 and 45 minutes post administration. The maximum BHPM-plasma concentrations were achieved 0,5 to 3 hours following the administration as a suppository.

Biotransformation

Following either oral or rectal administration, bisacodyl is rapidly hydrolysed to the active principle bis-(p-hydroxyphenyl)-pyridyl-2-methane (BHPM), mainly by esterases of the enteric mucosa.

Elimination

The plasma elimination half-life of BHPM glucuronide was estimated to be approximately 16,5 hours. 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.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose, Suppocire AM

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store at or below 25 °C.

Protect from light.

Store in well-closed containers.

6.5. Nature and contents of container

Opaque white, PVC laminated to polyethylene, film casings, in packs of individually sealed 5, 10, 50 or 250 suppositories (in strips of 5). Each opaque white suppository case has the name of the product and the applicant printed in red, on one side and is plain on the other side.

The strips are packed together with a package insert into a cardboard carton.

Not all packs or pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8. REGISTRATION NUMBER

E/11.5/1559

9. DATE OF FIRST AUTHORISATION

15 September 1997

10. DATE OF REVISION OF TEXT

5 May 2024

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

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