SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICALPRODUCT

Lax-Tab5 mg gastro-resistant tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 5 mg bisacodyl.

Excipient(s) with known effect
This product contains 26.3 mg lactose and 35.396 mg sucrose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gastro-resistant tablet.

Light yellow, round, gastro-resistant tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Short term relief of constipation.

Constipation, either chronic or of recent onset, whenever a stimulant laxative is required.

Bowel clearance before surgery or radiological investigation. Replacement of the evacuant enema in all its indications.

4.2 Posology and method of administration

Posology

Short-term treatment for constipation
Adults and children over 10 years: 1 to 2 coated tablets (5– 10 mg) daily before bedtime.

Children 4 – 10 years: 1 coated tablet (5 mg) daily before bedtime.

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.

For preparation of diagnostic procedures and preoperatively
For preparation of diagnostic procedures, in pre- and postoperative treatment when defaecation needs to be facilitated, Lax-Tab should be used under medical supervision.

Adults and children over 10 years: 2 coated tablets (10 mg) in the morning and 2 coated tablets (10 mg) in the evening.

Children aged 4 -10 years of age: 1 coated tablet (5 mg) in the evening.

Instructions for use
It is recommended to take the coated tablets at night to have a bowel movement the following morning. They should be swallowed whole with an adequate amount of fluid.

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

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

Lax-Tabis contra-indicated in patients with ileus, intestinal obstruction, acute abdominalconditions such as appendicitis, acute inflammatory bowel diseases, and severe abdominal pain associated with nausea and vomiting which may be indicative of the aforementioned severe conditions.

Lax-Tab is also contra-indicated in severe dehydration and in patients with known hypersensitivity to bisacodyl or any other ingredient of the product.

In case of hereditary conditions that may be incompatible with an excipient of the product (please refer to “Special warnings and precautions for use”) the use of the product is contraindicated.

4.4 Special warnings and precautions for use

As with all laxatives, Lax-Tab should not be used on a continuous daily basis for more than five days.If laxatives are needed every day, the cause of constipation should be investigated.

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) Lax-Tab should be discontinued and only be restarted under medical supervision.

Laxatives 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. 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.

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.

Lax-Tab should not be taken bychildren under 10 years without medical advice.

This product containslactose. If you have been told by your doctor that you have anintolerance to some sugars, contact your doctor beforetaking this medicinal product.

This product contains sucrose. If you have been told by your doctor that you have anintolerance to some sugars, contact your doctor before taking this medicinal product.

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. However, this situation only arises if excessive doses of Lax-Tab 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, Lax-Tab should not be used in pregnancy, especially the first trimester and during breast-feeding, unless the expected benefit is thought to outweigh any possible risk to the foetus and only on medical advice.

4.7 Effects on ability to drive and use machines

No studies on the effects of Lax-Tab 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).

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.

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 national reporting system.

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.

Laxatives when taken in chronic overdosemay 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 Lax-Tab, 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: Drugs for constipation, 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 intestineand 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

Following oral 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 a gastro-resistant 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. 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 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.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core
Lactose monohydrate
Starch
Povidone
Microcrystalline cellulose
Sodium starch glycolate
Colloidal silicon dioxide
Magnesium stearate
Talc

Coating
Methacrylic acid copolymer
Polyethylene glycol 6000
Silicon antifoam
Gelatin
Sucrose
Calcium carbonate
Quinoline yellow E104

6.2 Incompatibilities

None stated.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 30 ^{o}C. Protect from light and moisture.

6.5 Nature and contents of container

PVC/Aluminium blisters. Packsize of 50 gastro-resistant tablets.

6.6 Special precautions for disposal and other handling

None stated.

7. MARKETING AUTHORISATION HOLDER

Remedica Ltd
Aharnon Str., Limassol Industrial Estate,
3056 Limassol,
Cyprus

8. MARKETING AUTHORISATION NUMBER

05504/07537/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 24May 2012
Date of latest renewal:24November2020

10. DATE OF REVISION OF THE TEXT

04/07/2023