Bisacodyl Tablets BP 5 mg LINCODYL

COMPOSITION:

Each enteric coated tablet contains:
Bisacodyl BP 5 mg
Excipients Q.S.

Colour: Quinoline Yellow

THERAPEUTIC CLASS:

Stimulant Laxative

PHARMACOLOGICAL ACTION:

Bisacodyl is a locally acting laxative from the diphenylmethane derivatives group having a dual action. As a contact laxative, 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.

Pharmacokinetics: 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 410 hours post administration whereas the laxative effect occurred between 6 12 hours post 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. 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. Stool contained large amounts of BHPM (90% of the total excretion) in addition to small amounts of unchanged bisacodyl.

INDICATIONS:

LINCODYL is indicated for the treatment of occasional constipation, for use as bowel cleansing regimen, preparing the patient for surgery or for preparing the colon for x-ray or endoscopic examination.

CONTRAINDICATIONS:

LINCODYL 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. It is also contraindicated in severe dehydration and in patients with known hypersensitivity to bisacodyl or any other component of the product.

ADVERSE EFFECTS:

Common: abdominal cramps, abdominal pain, diarrhoea and nausea.

Uncommon: dizziness, haematochezia, vomiting, abdominal discomfort, anorectal

discomfort.

Rare: anaphylactic reactions, angioedema, hypersensitivity, dehydration, Syncope, colitis.

WARNING & PRECAUTIONS:

• LINCODYL should not be used in the presence of abdominal pain, nausea or vomiting.

- Frequent or prolonged use may result in dependence on laxatives and loss of normal bowel function. So, use of LINCODYL beyond 1 week is not recommended except on the advice of a doctor.
- Use should be discontinuing if rectal bleeding or failure to have a bowel movement persist after use of LINCODYL.

DOSAGE AND ADMINISTRATION:

Constipation:

Adults and children over 10 years old: 2 tablets at night; occasionally a higher dosage is required, and up to 3 or 4 tablets may be given.

Elderly: As for adults. It may be necessary to reduce the dosage under certain circumstances.

Children 3 to 10 years old: 1 tablet at night.

Children under 3 years old: Not recommended.

Before surgery, labour or hospital radiological examination:

Adults and children over 10 years old: 2 tablets on each of 2 nights before the anticipated procedure.

Elderly: As for adults. It may be necessary to reduce the dosage under certain circumstances.

Children 3 to 10 years old: 1 tablet on each of 2 nights before the investigation.

Children under 3 years old: Not recommended.

OVERDOSAGE:

Symptoms: Colicky lower abdominal pain with possible signs of dehydration, particularly in

the elderly and the very young Treatment: Gastric lavage.

DRUG INTERACTIONS:

Antacids or milk products may affect the absorption of bisacodyl.

Concomitant use with diuretics may increase the loss of electrolytes, particularly potassium, causing increased toxicity of cardioglycosides.

PRESENTATION:

Strip pack / Jar Pack

STORAGE CONDITION:

Store below 30°C. Protect from light.

SHELF LIFE:

36 Months

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Manufactured by:



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