1.6.1

Prescribing Information (Summary of Product Characteristics)

1.6.1.1 Name of the medicinal Product

Bisacodyl Tablets BP 5 mg

1.6.1.1.1 strength

5 mg/tablet

1.6.1.1.2 Pharmaceutical Form

Oral tablet

1.6.1.2 Qualitative and Quantitative Composition

1.6.1.2.1 Qualitative declaration

Bisacodyl BP

1.6.1.2.2 Quantitative declaration

Sr. No.	Ingredients Chemical Name	Specification	Quantity/ dosage unit (mg)	Reason for Inclusion
01	Bisacodyl	BP	Stimulant laxative	5.00
02	Lactose (Lactose Monohydrate)*	BP	Diluent	70.00
03	Maize Starch **	BP	Diluent/ Binder	10.00
04	Isopropyl Alcohol (IPA)	BP	Solvent	25.00
05	Povidone (PVPK30)	BP	Binder	5.00
06	Sodium Starch Glycolate (Type-A)	BP	Disintegrant	6.00
07	Purified Talc	BP	Glidant	3.00
08	Magnesium Stearate	BP	Lubricant	1.00
09	Acrycoat L-100	IHS	Enteric coating polymer	7.00

10	Titanium Dioxide	BP	Opacifier	0.10
11	Acetone	BP	Solvent for coating	50.00
12	Isopropyl Alcohol (IPA)	BP	Solvent for coating	87.50
13	Colour Quinoline Yellow Lake	IHS	Colorant	0.80
14	Diethyl Phthalate	BP	Plasticizer	1.25

Note:

* Increase in the weight of Bisacodyl BP due to assay compensation is to be compensated with Lactose (Lactose Monohydrate) BP.

** 7.0 % LOD Compensated.

1.6.1.2.3 Pharmaceutical Form

Oral, Coated Tablet

Yellow coloured, round shaped, Biconvex, enteric coated tablet plain on both side.

1.6.1.3 Clinical Particulars

1.6.1.3.1 Therapeutic 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.

1.6.1.3.2 Posology and Method of 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.

1.6.1.3.3 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.

1.6.1.3.4 Special Warnings and Special Precautions for Use

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.

Bisacodyl 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

1.6.1.3.5 Interaction with other medicinal products and other forms of interaction

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.

1.6.1.3.6 Fertility, Pregnancy and Lactation

No adequate data available.

1.6.1.3.7 Effects on ability to Drive and use Machines

No adequate data available.

1.6.1.3.8 Undesirable 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.

1.6.1.3.9 Overdose

Symptoms: Colicky lower abdominal pain with possible signs of dehydration, particularly in the elderly and the very young

Treatment: Gastric lavage.

1.6.1.4 Pharmacological Properties

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.

1.6.1.5 Pharmaceutical Particulars

1.6.1.5.1 List of Excipients

Lactose (Lactose Monohydrate) BP

Maize Starch BP

Isopropyl Alcohol (IPA) BP

Povidone (PVPK30) BP

Sodium Starch Glycolate (Type-A) BP

Purified Talc BP

Magnesium Stearate BP

Acrycoat L-100 IHS

Titanium Dioxide BP

Acetone BP

Isopropyl Alcohol (IPA) BP

Colour Quinoline Yellow Lake IHS

Diethyl Phthalate BP

1.6.1.5.2 Incompatibilities

Not applicable.

1.6.1.5.3 Shelf Life

36 months

1.6.1.5.4 Special Precautions for Storage

Store below 30°C. Protect from light.

1.6.1.5.5 Nature and Contents of Container

Strip pack / Jar Pack

1.6.1.5.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

1.6.1.6 Marketing Authorization Holder And Manufacturing Site Addresses

1.6.1.6.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

1.6.1.6.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

1.6.1.7 Marketing Authorization Number

To be included after obtaining first registration.

1.6.1.8 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

1.6.1.9 Date of Revision of the Text

1.6.1.10 Dosimetry (If Applicable)

Not Applicable

1.6.1.11 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable