Summary Product Characteristics (SmPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

BELAX 5mg Tablet (Bisacodyl 5mg)

1.1 Strength

Each Enteric-coated tablet contains:
Bisacodyl B.P 5mg

1.2 Pharmaceutical form

Enteric Coated Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

S.No	Name of raw material	Specification	Qty.per Tab(mg)	Purpose of use
1.	Bisacodyl	BP	5.10	Active
2.	Avicel pH 102	BP	15.3	Diluent
3.	Lactose (Spray Dried)	BP	35.0	Diluent
4.	Maize Starch (Dried)	BP	4.00	Disintegrant
5.	Magnesium Stearate	BP	0.60	Lubricant
6.	HPMC (15Cps)	BP	0.90	Polymer
7.	Isopropyl Alcohol	BP	7.890	Solvent
8.	Methylene Chloride	BP	24.398	Solvent
9.	Eudragit L-100	BP	3.156	Enteric material
10.	Talcum	BP	1.044	Glidant
11.	Titanium Dioxide	BP	0.511	Colouring agent
12.	Tartrazine Lake	BP	1.613	Colour
13.	PEG-6000	BP	0.559	Plasticizer
14.	D.I.water	BP	6.706	Solvent
15.	Isopropyl Alcohol	BP	41.028	Solvent

B.P : British Pharmacopoeia

*Removed after drying and does not present in the finished product

3. PHARMACEUTICAL FORM

Enteric coated tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For human medicinal use.

Constipation either chronic or recent onset. Bowel clearance before surgery, labour or radiological investigation.

4.2 Posology and method of administration

Constipation:
Adults and children over 10 years: 1 to 2 tablets at

night. Children 4-10 years: On medical advice only.

In preparation for radiological investigation and surgery:
Adults and children over 10 years: 2 tablets on each of the 2 nights before the investigation.

Route of administration: Oral use

4.3 Contraindications

Conditions where any laxative is contraindicated.

Bisacodyl should not be used in intestinal obstruction.

Hypersensitivity to Bisacodyl or to the constituents
listed. Do not use in conjunction with suppositories.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Patients with rare hereditary problems of fructose intolerance or sucrase-isomaltase insufficiency should not take this medicine.

4.4 Special warnings and precautions for use

The tablets should not be crushed or chewed but swallowed whole. Antacids should not be given within one hour after taking the tablets.
Prolonged use can precipitate the onset of an atonic non-functioning colon and hypokalaemia.
This product should not be used on a continuous daily basis for long periods. If laxatives are needed every day, then the cause of constipation should be investigated.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Do not use unless there are compelling reasons

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

May cause griping and abdominal cramp; these can be minimised by dosing adjustment.

4.9 Overdose

Gastric lavage should be performed where appropriate. Adequate hydration must be maintained and the serum potassium should be measured. Antispasmodics may be of some value. Particular care of fluid balance should be taken in the elderly and the young.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Bisacodyl is a stimulant laxative (ATC code: A06A B02) that increases intestinal motility. The product resulting from the hydrolysis of Bisacodyl is responsible for its laxative effect.

5.2 Pharmacokinetic properties

After oral administration a small amount is absorbed from the gastrointestinal tract and excreted in the urine as the glucuronide. About 3% of the glucuronide appears in the bile after about 10 hours but Bisacodyl is mainly excreted in the faeces.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bisacodyl	BP
Avicel pH 102	BP
Lactose (Spray Dried)	BP
Maize Starch (Dried)	BP
Magnesium Stearate	BP
HPMC (15Cps)	BP
Isopropyl Alcohol	BP
Methylene Chloride	BP
Eudragit	BP
Talcum	BP
Titanium Dioxide	BP
Tartrazine Lake	BP
PEG-6000	BP
D.I.water	BP

Isopropyl Alcohol	BP

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C in a dry place.

6.5 Nature and contents of container

Pack style : Blister pack of 10 x 10's tablets.
Primary Packing : 10 tablets in a blister of Alu-PVC foil.
Secondary Packing: Ten blisters along with a leaflet are inserted in printed outer carton

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

SUNLIGHT LINKS PHARM LTD
135,Brono Way,Ebutte-Metta
Lagos Nigeria

MANUFACTURED BY:
Rock Pharmaceutical Laboratories (Pvt) Ltd
134-B & 135-B,Nowshera Industrial Estate
Risalpur, Khyber Pakhtunkhwa, Pakistan

8 MARKETING AUTHORISATION NUMBER(S)

NAFDAC NO : B4-0722

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/09/2013

10 DATE OF REVISION OF THE TEXT

Not Applicable