SUMMARY OF PRODUCT CHARACTERISTICS OF BICOLEX 5 MG ENTERIC COATED TABLET

1. Name of the medicinal product

1.1 Proprietary Name

Bicolex Enteric coated tablet

1.2 Strength

Each tablet contains 5mg of Bisacodyl

2. Qualitative and quantitative composition

2.1 Qualitative declaration

Name of Active Ingredient
Bisacodyl

2.2 Quantitative declaration

Name of Active Ingredient	Quantity/tablet (mg)
Bisacodyl	5mg

Excipients with known effect

Qualitative declaration

Name of Excipients
Lactose BP

Quantitative declaration

Name of Excipients	Quantity/tablet
Lactose BP	30mg

For full list of Excipients, see section 6.1

3. Pharmaceutical

form Enteric coated

tablet **Product**

Description

Orange circular biconvex enteric coated tablet plain on both sides

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

It is recommended to start with the lowest dose. The dose might be adjusted up to the maximum recommended dose to produce regular stools. The maximum daily dose should not be exceeded.

Method of Administration

For oral use. The tablet should be swallowed whole and not crushed, with sufficient amount of liquid.

4.3 Contraindications

Bisacodyl 5 mg, gastro-resistant tablets are 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.

Bisacodyl 5 mg gastro-resistant tablets are also contra-indicated in severe dehydration and in patients with known hypersensitivity to bisacodyl or any other component of the product.

In case of hereditary conditions that may be incompatible with an excipient of

the use of the product is contraindicated.

4.4 Special warnings and precautions for use

As with all laxatives, Bisacodyl 5 mg gastro-resistant tablets should not be taken on a continuous daily basis for more than five days without investigating the cause of constipation.

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), bisacodyl should be discontinued and only be restarted under medical supervision.

Laxatives do not help with weight loss.

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 biscodyl itself.

There have been isolated reports of abdominal pain and bloody diarrhea occurring after taking bisacodyl. Some cases have been shown to be associated with colonic mucosal ischaemia.

Bisacodyl should not be taken by children under 10 years without medical advice.

Information about excipients

Bicolex tablets contain lactose as one of the excipients. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take 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 if excessive doses of bisacodyl are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

4.6 Fertility, Pregnancy and Lactation

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.

Breastfeeding:

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, bisacodyl should not be taken during 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.

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 bisacodyl 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

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 including ischaemic 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 and the general public are advised to report any suspected adverse reactions to the relevant drug authority regulator, through the relevant platforms.

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 overdose 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.

Therapy

After ingestion of oral forms of Bisacodyl 5 mg gastro-resistant tablets, 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Therapeutic class:

Laxative ATC code:

A06AB02

Bisacodyl is a locally acting laxative from diphenylmethane derivatives group having a dual action. As a contact laxative, for which also anti- resorptive 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

Following either oral or rectal 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 an enteric coated 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. In contrast, following the administration as a suppository, the laxative effect occurred on average approximately 20 minutes post administration; in some cases it occurred 45 minutes after administration. The maximum BHPM-plasma concentrations were achieved 0.5 – 3 hours following the administration as a suppository. Hence, 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.

5.3 Preclinical safety data

Not known.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose BP

Maize starch

BP Povidone

BP

Isopropyl alcohol BP

Magnesium stearate

BP ENTERIC

COATING

Instacoat super orange II

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30°C. Protect from light and moisture.

6.5 Nature and contents of container

PVC/Aluminium foil

Available in pack size of 100 tablets in a unit carton**,** with literature insert inside

6.6 Special precautions for disposal and other handling

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

7 Market Authorization Holder

Cosmos Limited

Rangwe Road; Off Lunga Lunga, Industrial Area

P.O Box 41433, GPO 00100-Nairobi

Kenya

Telephone: + (254-20) 2519603/4/5, 020 8042200/2/3/4/5
E-mail: admin@cosmos-pharm.com

8 Marketing Authorization Number

H91014

9 Date of First Registration/Renewal of

Registration Date of First Registration:

12th April 1991

10 Date of Revision of Text

October 2025