

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dulcolax 5mg Gastro-resistant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg of bisacodyl.

Excipients:

Lactose monohydrate 34.90mg

Sucrose 23.38mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet (tablet).

Circular, biconvex, yellow, sugar-coated, enteric-coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For evacuation of the colon in constipation and in preparation for radiological investigations.

4.2 Posology and method of administration

Short-term treatment for constipation:

Adults and children over 10 years: 1 to 2 coated tablets (5 - 10 mg) daily before bedtime, or 1 suppository (10 mg) daily for immediate effect.

Children 4 – 10 years: 1 coated tablet (5 mg) daily before bedtime, or 1 suppository (5 mg) daily for immediate effect.

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, DULCOLAX should be used under medical supervision. The tablets should be combined with suppositories in order to achieve complete evacuation of the intestine.

Adults and children over 10 years: 2 coated tablets (10 mg) in the morning and 2 coated tablets (10 mg) in the evening and 1 suppository (10 mg) on the following morning is recommended.

Children aged 4 - 10 years of age: 1 coated tablet (5 mg) in the evening and 1 suppository (5 mg) on the following morning is recommended.

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.

Suppositories are usually effective in about 20 minutes (usual range 10 to 30 minutes). Rarely the laxative effect has been reported 45 minutes after administration. They should be unwrapped and inserted into the rectum pointed end first.

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

DULCOLAX 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.

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

4.4 Special warnings and precautions for use

As with all laxatives, DULCOLAX 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) DULCOLAX should be discontinued and only be restarted under medical supervision.

Stimulant laxatives including DULCOLAX 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 DULCOLAX. The details available for these cases suggest that the events would be consistent with defaecation 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.

DULCOLAX Tablets contain a small amount of lactose (33.2 mg) in each tablet. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

DULCOLAX Tablets contain a small amount of sucrose (23.4 mg) in each tablet. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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 DULCOLAX are taken. Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides. The concomitant use of other laxatives may enhance the gastrointestinal side effects of DULCOLAX.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of bisacodyl in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

As a precautionary measure, it is preferable to avoid the use of bisacodyl during pregnancy, especially in the first trimester.

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, bisacodyl should not be taken 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 DULCOLAX 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 ($\geq 1/10$); common ($\geq 1/100$, $< 1/10$); uncommon ($\geq 1/1000$, $< 1/100$); rare ($\geq 1/10000$, $< 1/1000$); 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: vomiting, haematochezia (blood in stool), abdominal discomfort, anorectal discomfort.

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

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 are asked to report any suspected adverse reactions via HPRC Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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 DULCOLAX, 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

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 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 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.

After oral and rectal 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. Following the administration as a suppository, an average of 3.1% of the dose was recovered as BHPM glucuronide in the urine. Stool contained large amounts of BHPM (90% of the total excretion) in addition to small amounts of unchanged bisacodyl.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch (dried)
Modified starch (corn starch, oxidised)
Glycerol (85 %)
Magnesium stearate
Sucrose
Talc
Acacia (powdered)
Titanium dioxide (E171)
Methacrylic acid-methyl methacrylate copolymer (1:1)
Methacrylic acid-methyl methacrylate copolymer (1:2)
Castor oil
Macrogol 6000
Yellow iron oxide (E172)
White beeswax
Carnauba wax
Shellac

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

Keep container in the outer carton.

6.5 Nature and contents of container

Blister packs consisting of opaque white PVC/PVDC blister foil and aluminium foil (covering foil).

Blister packs consisting of colourless PVC blister foil and aluminium foil (covering foil).

Pack sizes of 10, 20, 30, 40, 50, 60, 80 and 100.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Opella Healthcare, France SAS, 157 avenue Charles de Gaulle, 92200 Neuilly-sur-Seine, France

8 MARKETING AUTHORISATION NUMBER

PA23180/018/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th June 1986

Date of last renewal: 5th June 2011

10 DATE OF REVISION OF THE TEXT

Novemeber 2023