

DATA SHEET

1 DULCOLAX

DULCOLAX® 5 mg enteric coated tablets

DULCOLAX 10 mg suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of DULCOLAX contains bisacodyl 5 mg.

Each suppository of DULCOLAX contains bisacodyl 10 mg.

For a full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Enteric coated tablet: smooth, round, shiny, brownish-yellow coated tablet.

Suppository: smooth, white or slightly yellowish torpedo-shaped suppository.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the use in cases of constipation.

In preparation for diagnostic procedures, in pre- and postoperative treatment and in conditions which require defecation, the use of DULCOLAX must be under medical supervision.

4.2 DOSE AND METHOD OF ADMINISTRATION

Unless otherwise prescribed by a physician, the following dosages are recommended:

Tablets

Adults and children over 10 years: 1 to 2 coated tablets at night (5 to 10mg)

Children 4 to 10 years: One coated tablet at night (5mg).

Notes: DULCOLAX tablets are coated. The tablets should be taken at night to produce evacuation the following morning. They should be swallowed whole with adequate fluid.

The coated tablets should not be taken together with products reducing the acidity of the upper gastrointestinal tract, such as milk, antacids or certain proton pump inhibitors, in order not to prematurely dissolve the enteric coating.

Suppositories

Adults and children over 10 years: One suppository (10mg)

Do not coat the suppository in any lubricant such as paraffin oil or paraffin jelly. By warming the suppository in the hand before it is removed from the foil wrapper, sufficient lubrication will be produced. Insert into the rectum the pointed end first. Suppositories are usually effective in about 20 minutes (range 10 to 30 minutes).

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.

Children aged 10 years or younger with chronic or persistent constipation should only be treated under the guidance of a physician.

4.3 CONTRAINDICATIONS

DULCOLAX should not be used by patients with ileus, intestinal obstruction, acute surgical abdominal conditions including appendicitis, acute inflammatory bowel diseases, and severe abdominal pain associated with nausea and vomiting which may be indicative of more severe conditions.

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

In case of rare hereditary conditions that may be incompatible with an excipient of the product (refer to Section 4.4 Special warnings and precautions for use) the use of the product is contraindicated.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

As with all laxatives, DULCOLAX should not be taken on a continuous daily basis for extended periods 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 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 DULCOLAX itself.

The use of suppositories may lead to painful sensations and local irritation, especially in patients with anal fissures and ulcerative proctitis.

One coated tablet contains 33.2 mg lactose, resulting in 66.4 mg lactose per maximum recommended daily dose for treatment of constipation in adults and children over 10 years of age. For radiographic examination this will result in 132.8 mg per maximum recommended daily dose in adults. Patients with rare hereditary conditions of galactose intolerance, e.g. galactosaemia, should not take this medicine.

One coated tablet contains 23.4 mg sucrose (saccharose), resulting in 46.8 mg sucrose (saccharose) per maximum recommended daily dose for treatment of constipation in adults and children over 10 years of age. For radiographic examination this will result in 93.6 mg per maximum recommended daily dose in adults. Patients with the rare hereditary condition of fructose intolerance should not take this medicine.

4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

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

There are no adequate and well-controlled studies in pregnant women. Long experience has shown no evidence of undesirable or damaging effects during pregnancy.

Nevertheless, as with all drugs, DULCOLAX should be taken during pregnancy only on medical advice.

Clinical data show that neither the active moiety of bisacodyl BHPM (bis-(p-hydroxyphenyl)-pyridyl-2-methane) nor its glucuronides are excreted into the milk of healthy lactating human females.

Thus, DULCOLAX can be used during breast-feeding.

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.

Immune system disorders

Anaphylactic reactions, angioedema, hypersensitivity.

Metabolism and nutrition disorders

Dehydration

Nervous system disorders

Dizziness, syncope.

Dizziness and syncope occurring after taking bisacodyl appear to be consistent with a vasovagal response (e.g., to abdominal spasm, defecation).

Gastrointestinal disorders

Abdominal cramps, abdominal pain, diarrhoea, vomiting, nausea, haematochezia (blood in stool), abdominal discomfort, anorectal discomfort, colitis including ischaemic colitis.

Reporting of suspected adverse reactions.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>

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.

DULCOLAX, as with other 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.

Treatment

Within a short time after ingestion of oral forms of DULCOLAX, absorption can be minimized 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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Actions

Bisacodyl, the active ingredient of DULCOLAX, is a locally acting laxative from the diphenylmethane derivatives group. It is a contact laxative, for which antiresorptive hydragogue laxative effects have been described. After metabolism by hydrolysis in the large intestine, the active form of bisacodyl stimulates peristalsis of the colon and promotes 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.

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 data sheet.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Coated tablets: Lactose monohydrate, maize starch dried, glycerol, magnesium stearate, sucrose, talc, acacia, titanium dioxide, methacrylic acid-methyl methacrylate copolymer (1:1) and methacrylic acid-methyl methacrylate copolymer (1:2), Castor oil, macrogol 6000, iron oxide yellow (E172), beeswax white, carnauba wax, shellac, maize starch (soluble).

Suppositories: Hard fat (Witepsol W45)

6.2 INCOMPATIBILITIES

None.

6.3 SHELF LIFE

Suppositories: 5 years.

Tablets: 3 years.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store in a safe place out of reach of children.

Store below 30° C.

6.5 NATURE AND CONTENTS OF CONTAINER

Suppository: 10mg, foil wrapped and carry the name DULCOLAX in packs of 6 and 50.

Tablets: 5mg, blister packs of 30 and 100.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

None.

7 MEDICINE SCHEDULE

Pharmacy only medicine

8 SPONSOR

sanofi-aventis new zealand ltd
Level 8, James and Wells Tower
56 Cawley Street
Ellerslie, Auckland
New Zealand

Toll-free: 0800 283 684

9 DATE OF FIRST APPROVAL

5 mg Tablet: 31/12/1969

10 mg suppository: 31/12/1969

10 DATE OF REVISION OF THE TEXT

29 August 2017

Source Document BPI No.: 0074-08 dated 20jul17

Table 1 - 1.1 SUMMARY TABLE OF CHANGES

New Zealand Data Sheet prepared in accordance with the updated data sheet SPC-style format.

Source documents used:

New Zealand Data Sheet – dated 4 October 2013

SECTION	ADDITIONAL TEXT ADDED
All	Update to headings and reference to align with SPC-style format
1 PRODUCT NAME	Addition of strength and dosage form
2. QUALITATIVE AND QUANTITATIVE COMPOSITION	New Section
3 PHARMACEUTICAL FORM	Reworded visual description to align with CMI
4.4 Special warnings and precautions for use	Addition of precaution regarding weight loss.
4.5 Interaction with other medicines and other forms of interaction	Additional warning regarding concomitant use of other laxatives.
4.8 Undesirable effects	Additional adverse reactions. Addition of reporting of suspected adverse reactions sub-section.
4.9 Overdose	Addition of Poison Centre contact details.
5.3 Preclinical safety data	New Section
6.2 Incompatibilities	New Section
6.3 Shelf Life	New Section
6.5 Nature and contents of container	Reworded pack type and size information
6.6 Special precautions for disposal and other handling	New Section
8 SPONSOR	Change to sponsor name & address to reflect Sanofi assuming sponsorship of the product from Boehringer Ingelheim.
9 DATE OF FIRST APPROVAL	New Section

DULCOLAX® is a registered trademark