COMPANY CORE DATA SHEET
No. 0074-08

DULCOLAX®

COMPOSITION

1 coated tablet contains 5 mg

4,4'-diacetoxy-diphenyl-(pyridyl-2)-methane (= bisacodyl)

Excipients:**
Coated tablets: lactose monohydrate, maize starch dried, starch soluble, glycerol, magnesium stearate, sucrose (saccharose), PCID 83365*** talc, acacia, titanium dioxide, methacrylic acid-methyl methacrylate copolymer (1:1) and methacrylic acid-methyl methacrylate copolymer (1:2), castor oil, macrogol 6000, ferric oxide yellow (E172), beeswax white, carnauba wax, shellac

PRODUCT DESCRIPTION
Round, beige-yellow, biconvex sugar/enteric-coated tablets with a smooth, shiny surface and a white core.

INDICATIONS

For use in patients suffering from constipation.
For preparation of diagnostic procedures, in pre- and postoperative treatment and in conditions which require defecation to be facilitated.

DOSAGE AND ADMINISTRATION

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

For constipation
Enteric coated tablets
Adults and children over 10 years: 1 - 2 coated tablets (5 - 10 mg) daily

Paediatric population:
Children 6 - 10 years: 1 coated tablets (5 mg) daily

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.

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 reducing the acidity of the upper gastrointestinal tract, such as milk, antacids or proton pump inhibitors, in order not to prematurely dissolve the enteric coating.

For preparation of diagnostic procedures and preoperatively
For preparation of diagnostic procedures, in pre- and postoperative treatment and in medical conditions which require defecation to be facilitated, DULCOLAX® should be used under medical supervision.

In order to achieve complete evacuation of the intestine the DULCOLAX® dosage recommended for adults is two to four coated tablets the night before the examination,-followed by one suppository in the morning of the examination.

Paediatric population
For children 6 years of age and over, one coated tablet in the evening and one paediatric suppository on the following morning is recommended.

Children under 6 years:
Chhildren under 6 years should not take DULCOLAX® without medical advice.

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 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 (please refer to "Special Warnings and Precautions") the use of the product is contraindicated.

SPECIAL WARNINGS AND PRECAUTIONS
As with all laxatives, DULCOLAX® should not be taken on a continuous daily basis or 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.

Children should not take DULCOLAX® without medical advice.

Stimulant laxatives including DULCOLAX® do not help with weight loss (see Section Pharmacological 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 bisacodyl itself.

Coated tablets
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.

This product contains tartrazine which may cause allergic reactions. Yellow discolouration of urine, sweat, and skin was reported.

INTERACTIONS
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®

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.

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

Lactation
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.

Fertility
No studies on the effect on human fertility have been conducted.

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.

SIDE 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, nausea, haematochezia (blood in stool), vomiting, abdominal discomfort, anorectal discomfort, colitis including ischaemic colitis.

Reporting of suspected adverse reactions
Report immediately if you experience any adverse reaction or undesirable condition during and after using the medicinal product to farmakovigilans@kalventis.com.

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.

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.

PHARMACOLOGICAL PROPERTIES
Bisacodyl is a locally acting laxative from the diphenylmethane derivatives group. As a contact laxative, for which also antiresorptive hydragogue effects have been described, bisacodyl stimulates, after hydrolysis in the large intestine, 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.

PHARMACOKINETICS

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.

AVAILABILITY

Enteric-coated tablets of 5 mg

Box, 20 envelopes @ 1 blister @ 4 tablets	Reg. No. DTL1821207915A1
Box contains 1 blister @ 10 tablets	Reg. No. DTL1821207915A1

Dulcolax tablet:
Store below 30°C, in a well-closed container. Store in a safe place out of the reach of children.

P. No. 1
Awas! Obat Keras
Bacalah aturan memakainya

Manufactured by:
PT Kalventis Sinergi Farma
Jakarta, Indonesia

Under license from:
Opella Healthcare International SAS, France

Revision date: 10 March 2025

Dulcolax®
Bisacodyl

Apa itu Dulcolax®?
Dulcolax® mengandung bisacodyl, obat pencahar yang bekerja lokal di usus besar, efektif mengatasi sembelit (susah BAB) dan membantu kondisi lain yang memerlukan pengeluaran feses (persiapan prosedur diagnostik, sebelum dan sesudah operasi).

Sediaan Dulcolax	Kekuatan	Deskripsi Produk
Tablet salut selaput 	5 mg	Tablet salut gula/enterik berbentuk cembung bulat berwarna kuning krem dengan permukaan halus mengkilat dan inti berwarna putih

Kapan dan Bagaimana Cara Penggunaan Dulcolax®?

	Dosis untuk sembelit*	Cara Pemakaian**
Dewasa dan anak >10 tahun	1-2 tablet	Konsumsi malam hari sebelum tidur dengan air secukupnya 
Anak 6-10 tahun	1 tablet	

*Hubungi dokter untuk dosis pada prosedur diagnostik sebelum dan sesudah operasi
**Mulai dengan dosis terendah. Naikkan dosis tablet pada dewasa jika diperlukan. Jangan melebihi dosis yang dianjurkan.

Bagaimana Dulcolax® Bekerja?
Dulcolax® bekerja dalam 3 langkah:

- ✓ **MENSTIMULASI** pergerakan usus
- ✓ **MELUNAKKAN** feses
- ✓ **MELANCARKAN** BAB

Dulcolax® tablet bekerja dalam 6-12 jam setelah pemberian

Apa yang Perlu Diperhatikan dalam Penggunaan Dulcolax®?

Jangan gunakan Dulcolax®:

Opella.

Bersamaan dengan susu, antasida, PPI, diuretik, adreno-kortikosteroid, serta bersamaan dengan obat pencahar lain.

Secara terus menerus tanpa mengetahui penyebab sembelit

Jika Anda mengalami penyumbatan dan radang usus, nyeri perut hebat, dehidrasi berat, atau alergi terhadap bisacodyl atau bahan lain yang terkandung dalam obat ini.

Dulcolax® tidak membantu menurunkan berat badan. Dulcolax® tidak efektif dalam mempengaruhi penyerapan kalori dan nutrisi esensial pada usus halus.

Apa Efek Samping Dulcolax® serta Penggunaannya pada Ibu Hamil dan Menyusui?

Penggunaan Dulcolax® dalam kehamilan harus atas petunjuk dokter.

Dulcolax® dapat digunakan selama menyusui.

Dulcolax® dapat mempunyai efek samping berupa reaksi alergi ringan hingga berat (anafilaksis), kejang dan nyeri perut, diare, mual/muntah, dehidrasi, pusing dan/atau pingsan, tidak nyaman pada perut dan anus, serta radang usus besar (kolitis). Pengguna Dulcolax® dapat mengalami adanya darah dalam tinja yang biasanya ringan dan dapat menghilang dengan sendirinya.
Overdosis pengunaan Dulcolax® dapat mengakibatkan diare, kram perut, kehilangan cairan dan elektrolit berlebihan. Jika mengalami gejala-gejala tersebut, segera berkonsultasi ke dokter.

Apakah boleh mengendarai dan menjalankan mesin selama minum obat ini?
Dulcolax tidak memiliki efek samping yang mempengaruhi kemampuan mengemudi dan menggunakan mesin.

Pelaporan efek samping
Segera laporkan apabila Anda mengalami keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat kepada farmakovigilans@kalventis.com. Anda dapat membantu memberikan informasi terkait keamanan obat ini.

Kemasan & Cara Penyimpanan

Kemasan
Tablet salut enterik 5 mg

Dus berisi 20 amplop @ 1 blister @ 4 tablet	Reg. No. DTL1821207915A1
Dus berisi 1 blister @ 10 tablet	Reg. No. DTL1821207915A1

Penyimpanan
Simpan di bawah suhu 30°C, dan di dalam wadah yang tertutup rapat. Simpan ditempat yang aman, jauh dari jangkauan anak-anak.

P. No. 1
Awas! Obat Keras
Bacalah aturan memakainya

DISETUJUI OLEH BPOM: 30/07/2025

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Opella.

Diproduksi oleh:
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Jakarta, Indonesia

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