Bisacodyl Dulcolax®

What is Bisacodyl (Dulcolax®) ?

Bisacodyl (Dulcolax®) is a locally acting laxative from the diphenylmethane derivatives group.
As a contact laxative, bisacodyl stimulates peristalsis of the colon and promotes accumulation of water in the colonic lumen which leads to stimulation of defecation, reduction of transit time and softening of 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.

Bisacodyl (Dulcolax®) is indicated in patients suffering from constipation and for preparation of diagnostic procedures, in pre- and post-operative treatment and in conditions which require defecation to be facilitated.

What is contained in Bisacodyl (Dulcolax®) ?

1 coated tablet contains ..... 5 mg
1 suppository contains ..... 10 mg
1 pediatric suppository ..... 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), 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 Suppositories: hard fat Witepsol W45

How does Bisacodyl (Dulcolax®) work ?

The laxative effect of Bisacodyl (Dulcolax®) occurs upon contact with the colonic mucosa where it stimulates the sensory nerve endings that results to increased peristaltic contractions of the large intestine to produce soft well-formed stools. This results in a stimulation of defecation, reduction of transit time, and a softening of the stool. It is a reversible reaction wherein colonic function would return to its normal condition after defecation occurs.

The tablets usually exert a laxative effect within 6 – 12 hours after intake. The suppositories usually take effect in about 20 minutes (range 10 to 30 minutes); in some cases, it occurs 45 minutes after administration.

How much Bisacodyl (Dulcolax®) should be taken ?

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

Adults and Children > 10 years:	**1 to 2 coated tablets (5 – 10 mg) daily or 1 suppository (10 mg) daily**
Children 4 –10 years old:	**1 coated tablet (5 mg) daily or 1 pediatric suppository (5 mg) daily**
Children under 4 years old:	**1 pediatric suppository (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.
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Children aged 10 years or younger with chronic or persistent constipation should only be treated under the guidance of a physician.
It is recommended to take the enteric coated tablets at night to promote 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.
Suppositories should be unwrapped and inserted into the rectum, pointed end first.

For preparation of diagnostic procedures, in pre- and post-operative treatment and in medical conditions which require defecation to be facilitated, Bisacodyl (Dulcolax®) should be used under medical supervision.
Bisacodyl (Dulcolax®) coated tablets should be combined with the suppositories in order to achieve complete evacuation of the intestine.

Adults:	**2 – 4 coated tablets the night before and 1 adult suppository in the morning of the examination**
Children 4 years of age and over	**1 coated tablet the night before and 1 pediatric suppository on the following morning**

To which patients should Bisacodyl (Dulcolax®) not be used ?

Bisacodyl (Dulcolax®) should not be given to patients with ileus, intestinal obstruction, acute abdominal conditions including appendicitis and acute inflammatory bowel diseases and severe abdominal pain associated with nausea and vomiting which may be indicative of severe conditions.
Bisacodyl (Dulcolax®) is also contraindicated in severe dehydration and in patients with known hypersensitivity to bisacodyl or any other component of the product.
In cases of rare hereditary conditions that may be incompatible with an excipient of the product, the use of the product is contraindicated.

As with all laxatives, Bisacodyl (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) Bisacodyl (Dulcolax®) should be

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Dulcolax®

discontinued and only be restarted under medical supervision.
Stimulant laxatives including Bisacodyl (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 Bisacodyl (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.
The use of suppositories may lead to painful sensations and local irritation, especially in patients with anal fissure and ulcerative proctitis.
Patients with rare hereditary conditions of galactose intolerance, e.g. galactosaemia, and fructose intolerance should not take this medicine.
No studies on the effects of Bisacodyl (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.

What is the effect of giving Bisacodyl (Dulcolax®) together withother medications ?

The concomitant use of diuretic and adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of Bisacodyl (Dulcolax®) are taken. If so, electrolyte imbalance may increase the sensitivity to cardiac glycosides.
The concomitant use of other laxatives may enhance the gastrointestinal side effects of Bisacodyl (Dulcolax®).

Can Bisacodyl (Dulcolax®) be used during 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, Bisacodyl (Dulcolax®) should be taken during pregnancy only on medical advice.

Bisacodyl (Dulcolax®) can be used during breast-feeding.

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

What are the possible side effects from Bisacodyl (Dulcolax®) ?

The most commonly reported adverse reactions during treatment with Bisacodyl (Dulcolax®) are abdominal pain and diarrhoea.
The following episodes may occur:
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, bdominal discomfort, anorectal discomfort, colitis, including ischaemic colitis.

Overdosage: High doses usually result to watery stools (diarrhoea), abdominal cramps and a clinically significant loss of fluid, potassium, and other electrolytes.
Bisacodyl (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.

After ingestion of oral forms of Bisacodyl (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.

How is Bisacodyl (Dulcolax®) available ?

Bisacodyl (Dulcolax®) is available in:
Sugar/enteric coated tablets of 5 mg@..... Pack of 120's
Suppositories of 10 mg* ..... Pack of 50's
Pediatric Suppositories of 5 mg* ..... Pack of 50's

Store tablets at temperatures not exceeding 30°C.
Store 5 mg suppositories at temperatures not exceeding 30°C.
Store 10 mg suppositories at temperatures not exceeding 25°C.

Reporting of Side Effects or any Suspected Adverse Event
For suspected adverse drug reaction, report to the FDA: **www.fda.gov.ph.**If you experience any side effects with the use of this product, you are advised to seek medical attention. You are also encouraged to report any side effects to Sanofi Philippines Pharmacovigilance Unit via email at **PV.Philippines@sanofi.com.** By reporting side effects, you can help provide more information on the safety of this product.

@Manufactured by
PT. Boehringer Ingelheim Indonesia
Jl. Lawang Gintung No. 89, Bogor, Indonesia

*Manufactured by
Istituto De Angeli S.r.l.
Loc. Prulli, 103/C, 50066 Reggello (FI), Italy

Imported by
Opella Healthcare Philippines, Inc.
21st, 22nd and 23rd Floors, One World Place,
32nd St., Bonifacio Global City, Taguig City

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DR-XY42393 - 5 mg Tablet
Date of last renewal: 08 August 2018
DR-XY44940 - 5 mg Suppository
Date of last renewal: 17 DEC 2020
DR-XY44557 - 10 mg Suppository
Date of last renewal: 18 MAY 2020

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Store in a safe place out of the reach of children!

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71522-05S

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Digital - Packaging - Development

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File information

GMID code:	653616
Plant PM code:	1060033030
Second Plant PM code:	71522-05S
Version of artwork:	V2
PM type:	PI
Market:	PH
Format:	150 x 210 mm
Issue date of artwork:	23/Apr/2021
Print colors:	Pan 357
Number of print colors:	1
Used font:	Bliss Pro
Min. font size:	5 pt
p2e number:	931641-U04

Technical colors

Diecut-Legendcase		Free area		Glue points	

Code information

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