Dulcolax®

Composition
1 coated tablet contains 5 mg
4,4'-diacetoxy-diphenyl-(pyridyl-2)-methane (= bisacodyl)

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

Pharmacologival properties
ATC code: A06AB02
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 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.

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

For preparation of diagnostic procedures and preoperatively
Should only be used under medical supervision.
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.

When using DULCOLAX to prepare the patient for radiographic examination of the abdomen or employing it preoperatively, tablets should be combined with suppositories in order to achieve complete evacuation of the intestine.

In the management of constipation, once regularity has been restarted dosage should be reduced and can usually be stopped.

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.

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 occuring 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.

Special 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.

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.

Children should not take DULCOLAX without medical advice.

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.

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.
The usual precautions regarding the use of drugs during pregnancy, particularly during the first trimester, should be observed.

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.

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 Precautions") the use of the product is contraindicated.

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®.

Overdosage
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.

Availability of pack sizes
Dulcolax Tablet 5mg: Box of 30 or 200 coated tablets.
Not all pack sizes may be marketed.

Storage condition
Store below 30ºC.

Please consult your doctor or pharmacist for further information.
Please refer to packaging for information on shelf-life.

Name and address of manufacturer
Mfd. by
Delpharm Reims
Reims France

Product registrant
In Singapore:
Opella Healthcare Singapore Pte Ltd
38 Beach Road #18-11
Singapore 189767

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