IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PPA1151/045/002
Case No: 2076834

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Imbat Limited

Unit L2, **North Ring Business Park**, **Santry**, **Dublin 9**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Dulcolax 10mg Suppositories

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **20/05/2010** until **21/06/2012**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dulcolax 10mg Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains 10 mg of bisacodyl.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suppository
Product imported from Greece
Smooth, white torpedo-shaped suppositories

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

1. In Constipation:
Adults and Children over 10 years: One 10mg suppository to be administered in the morning.

Children under 10 years: One 5mg suppository to be administered under medical supervision only.

Suppositories are usually effective in about 30 minutes.

A suppository should be unwrapped and inserted into the rectum pointed end first.

2. For preparation for diagnostic procedures and preoperatively:
When using Dulcolax to prepare the patient for radiographic examination of the abdomen or employing it preoperatively, Dulcolax Tablets 5mg should be combined with suppositories in order to achieve complete evacuation of the intestine.

Adults and children over 10 years: Two to four tablets the night before and insert one 10mg suppository the following morning.

Children aged 4 -10 years: One tablet the night before and insert one 5mg suppository the following morning.

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 surgical 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 a known hypersensitivity to bisacodyl or any other component of the product.
Dulcolax Suppositories should not be used when anal fissures or ulcerative proctitis with mucosal damage are present.

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.
Dulcolax Suppositories should not be used when anal fissures or ulcerative proctitis with mucosal damage are present.

Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.
Dizziness and / or syncope have been reported in patients during defecation, consistent with defecation syncope (or syncope attributable to straining at stool), or with a vasovagal response to abdominal pain which may be related to the constipation that prompted these patients to resort to the use of laxatives.
The use of suppositories may lead to painful sensations and local irritation, especially in anal fissures or ulcerative proctitis.
Dulcolax should not be taken by children under 10 years without medical advice.

4.5 Interaction with other medicinal products 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 increase sensitivity to cardiac glycosides.

4.6 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.
There is no evidence as to whether bisacodyl is excreted into breast milk.
Nevertheless, as with all medicines, Dulcolax should not be taken in pregnancy, especially the first trimester, and during breast feeding unless the expected benefit is thought to outweigh any possible risk and only on medical advice.

4.7 Effects on ability to drive and use machines

Not stated.

4.8 Undesirable effects

Adverse events have been ranked under headings of frequency using the following convention: Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1000, <1/100); rare (≥1/10000, <1/1000); very rare (<1/10000)
Not known – incidence cannot be estimated from the available data.

Immune system disorders
Not know: anaphylactic reactions, angioneurotic oedema and other hypersensitivity.

Gastrointestinal disorders
Uncommon: vomiting.

Common: Abdominal discomfort, abdominal pain, abdominal cramps, nausea and diarrhoea.
Not known: colitis.

Local irritation has been reported when the suppository formulation has been administered.

4.9 Overdose

Symptoms:
If high doses are taken diarrhoea, abdominal cramps and a clinically significant loss of 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:
Within a short time after ingestion of oral forms of Dulcolax absorption can be minimised or prevented by inducing vomiting. Otherwise, gastric lavage should be performed. Replacement of fluids and correction of electrolyte imbalance (particularly hypokalaemia) may be required. This is especially important in the elderly and the young. Administration of antispasmodics may be of some value.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Bisacodyl is a locally acting laxative from the triarylmethane group, which after bacterial cleavage in the colon, has the dual-action of stimulating the mucosa of both the large intestine causing peristalsis and of the rectum causing 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.

5.2 Pharmacokinetic properties

Hydrolysis of bisacodyl by enzymes of the enteric mucosa forms desacetylbisacodyl which is absorbed and excreted partly via urine and bile as glucuronide. By bacterial cleavage the active form, the free diphenol, is formed in the colon. Formulations of bisacodyl which are resistant to gastric and small intestinal juice, like Dulcolax sugar-coated tablets, reach the colon without any appreciable absorption and therefore avoid enterohepatic circulation. Consequently, these oral forms have an onset of action between 6 - 12 hours after administration.
Suppository formulations of bisacodyl have an onset of action within 15 - 30 minutes, although in some cases it may be prolonged to 15 - 60 minutes. The onset of action is determined by the release of the active substance from the preparation.
After administration, only small amounts of the drug are systemically available. Urinary excretion reflects low systemic burden after oral and rectal administration.
There is no relationship between the laxative effect and plasma levels of the active diphenol.

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

Hard fat (Adeps solidus).

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25ºC.
Keep the blister in the outer carton.

6.5 Nature and contents of container

Over-labelled outer containing blister strips.
Pack sizes of 6

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 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/45/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 22nd June 2007

10 DATE OF REVISION OF THE TEXT

May 2010