For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

BISACODYL TABLET/ SUPPOSITORY
DULCOFLEX®

Abridged Prescribing Information

COMPOSITION - Each enteric –coated tablet contains -Bisacodyl IP - 5 mg, Excipients q.s.
Each 5 mg Suppository contains – Bisacodyl IP - 5 mg, Excipients q.s.
Each 10 mg Suppository contains – Bisacodyl IP - 10 mg, Excipients q.s.

THERAPEUTIC INDICATION - 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 & ADMINISTRATION – Unless otherwise prescribed by the physician, the following dosages are recommended: 1 - 2 coated tablets (5 - 10 mg) daily. Or 1 suppository (10 mg) daily.

SAFETY-RELATED INFORMATION
CONTRAINDICATIONS – DULCOFLEX® 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. DULCOFLEX® is also contraindicated in severe dehydration and in patients with known hypersensitivity to bisacodyl or any other component of the product.
PREGNANCY & LACTATION – Pregnancy - There are no adequate and well-controlled studies in pregnant women. **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, DULCOFLEX® can be used during breast-feeding.
SPECIAL WARNINGS AND PRECAUTIONS FOR USE – Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.
ADVERSE REACTIONS : 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.

For full prescribing information please contact: Opella Healthcare India Private Limited, Unit 1104, 11th Floor, Godrej Two, Pirojshanagar, Eastern Express Highway, Vikhroli East, Mumbai – 400079, Maharashtra

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