Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Toilax Micro Enema 10 mg/5 ml Rectal Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Bisacody.
Each micro-enema contains 2mg/ml of bisacodyl.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Rectal suspension (enema).
Disposable yellow enema applicator tube with elongated tube nozzle containing a white/grey ointment like preparation.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Toilax is indicated in adults and children over 10 years for evacuation of the colon in constipation for short term use only. Prior to surgical and diagnostic procedures and in obstetrics prior to delivery. Use for other purposes must be under medical supervision.

4.2 Posology and method of administration

Children aged 10 years or younger with chronic constipation should only be treated under the guidance of a physician. Bisacodyl should not be used in children below 2 years of age.

Short-term treatment for constipation:
Adults and children over 10 years: One micro enema (10 mg) applied to the rectum for immediate effect.
Children 2 - 10 years: Half a micro enema (5 mg) applied to the rectum for immediate effect.

For preparation of diagnostic procedures and preoperatively:
Should only be used under medical supervision
Adults and children over 10 years: The recommended dose is one micro enema (10 mg) rectally on the morning of the examination, (preceded the previous day by two 5 mg bisacodyl oral tablets in the morning and two 5 mg bisacodyl oral tablets again in the evening).

Children 4-10 years of age: The recommended dose is half a micro enema (5 mg) rectally on the morning of the examination, (preceded the previous evening by one 5 mg bisacodyl oral tablet).

Older people: Dose as in adults for both indications. In some cases no more than 5 mg should be administered.

The dosage refers to one administration per day. Long term use cannot be recommended.

Make sure the enema is at room temperature before instillation.

Micro enema should be administered in the morning.

When used in children, the product nozzle should be inserted half its length only.

4.3 Contraindications

1. Undiagnosed painful abdominal symptoms which may be due to acute appendicitis and or other acute surgical conditions such as intestinal obstruction or acute inflammatory bowel disease.

2. Ileus.
3. In severe dehydration states with water and electrolyte depletion.
4. Anal fissures, ulcerative proctitis with mucosal damage and ulcerated haemorrhoids.
5. Hypersensitivity to bisacodyl or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

1. If laxatives are needed every day, the cause of the constipation should be investigated.
2. Excessive and prolonged use is dangerous and may result in diarrhoea leading to dehydration, electrolyte imbalance such as hypokalaemia, malabsorption and protein losing enteropathy.
3. Prolonged and daily use may precipitate the onset of rebound constipation.
4. In anal fissures and ulcerative proctitis, the use of micro enema suspension may lead to pain and perianal bleeding.
5. The development of laxative dependence, chronic constipation and loss of bowel function – "cathartic colon" with atony, dilatation, and resemblance of ulcerative colitis or proctitis – is also possible.
6. Dizziness and/or syncope has been reported during the use of bisacodyl. The event could be related to defecation syncope or to a vasovagal response to abdominal pain.
7. Haematochezia may be seen but is usually mild and self-limiting; more severe bloody diarrhoea may be associated with colonic mucosal ischaemia.

This medicinal product contains less than 1 mmol (23 mg) sodium per 5ml Rectal Suspension, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interactions

Concomitant use with diuretics, cardiac glycosides or adrenocorticosteroids may enhance the electrolyte imbalance.

4.6 Fertility, pregnancy and lactation

Pregnancy
Although no teratogenic effects have been detected in animals or human infants, bisacodyl should not be used during pregnancy, especially the first trimester, unless the expected benefits outweigh the possible risks to the foetus.

Breast-feeding
Breast feeding is not recommended as there is insufficient data on the excretion of Bisacodyl and/or its metabolites in breast milk.

4.7 Effects on ability to drive and use machines

No studies on the effects of bisacodyl 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.

4.8 Undesirable effects

At recommended doses, adverse reactions are unlikely to occur. Abdominal pain and cramping and cases of nausea and vomiting have been reported. Haematochezia may be seen and also rare cases of colitis including ischaemic colitis have been reported. Rectal formulations can cause local irritation and mild proctitis. Mild, transient skin reactions have rarely been described in association with bisacodyl administration. Dizziness and syncope have been reported.

Frequency convention by MedDRA: Common (>1/100), uncommon (>1/1000 – <1/100), rare (<1/1000) or not known (cannot be estimated from the available data).

Organ group	*Common*	*Uncommon*	*Rare*	*Not known*
Immune system disorders			Hypersensitivity including angioedema and anaphylactoid reactions	
Nervous system disorders				Dizziness syncope

Gastrointestinal disorders	Abdominal pain and cramping, nausea	Local irritation, pain and bleeding, mild proctitis	Vomiting	Haematochezia, colitis including ischaemic colitis
Skin and subcutaneous tissue disorders			Mild, transient skin reactions	

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the HPRA website: www.hpra.ie or email: medsafety@hpra.ie.

4.9 Overdose

Overdose of bisacodyl is possible if excessive quantities are taken or if the recommended doses are administered for prolonged periods.

Symptoms of overdose include abdominal pain and diarrhoea. Electrolyte imbalances such as hypokalaemia with muscular weakness and ECG alterations may develop.

Absorption can be minimised or prevented, if an overdose has been taken and / or the product ingested orally, by inducing vomiting within a short time of ingestion. Otherwise gastric lavage should be performed. Activated charcoal should be administered.

If high doses are taken watery stools (diarrhoea), a clinically significant loss of potassium and other electrolytes can occur and treatment consists of adequate replacement of fluids and correction of any electrolyte disturbances. This is especially important in the older people and the young.

Administration of antispasmodics may be of some value.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Enemas, ATC code: A06AG02
Bisacodyl is a locally acting laxative from the triarylmethane group, which after metabolism by hydrolysis stimulates the mucosa of the large intestine causing peristalsis of the colon.

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 reach the colon without any appreciable absorption and therefore avoid enterohepatic circulation. Consequently, orally administered formulations have an onset of action from between 6-12 hours. Micro enema formulations of bisacodyl have a short 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.

There is no relationship between the laxative effect and plasma levels of the active diphenol.

5.3 Preclinical safety data

Testing in rats and mice showed no carcinogenic effect. Bisacodyl has shown no mutagenic or genotoxic potential.

No teratogenic effect could be found in rats dosed with 10-15 mg bisacodyl per kilogram per day.

The safety of bisacodyl has not been studied in descriptive animal toxicity tests. Induction of cell proliferation in intestinal epithelia has been described in animal experiments after chronic bisacodyl treatment. Dietary supplements with 0.3% bisacodyl for 32 weeks was found to induce both calculi and epithelial proliferative lesions in the urinary bladder of rats.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 3000
Macrogol 4000
Macrogol 400
Citric acid monohydrate
Sodium Citrate
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Keep the applicators in the outer carton.

6.5 Nature and contents of container

Disposable enema applicator tube with elongated tube nozzle containing 5 ml suspension packed as 5 or 50 single-use 5ml plastic enemas in a cardboard outer container.

6.6 Special precautions for disposal and other handling

For single use only.
Any unused medicinal product or waste material should immediately be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

8 MARKETING AUTHORISATION NUMBER

PA1327/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 21 January 2006

10 DATE OF REVISION OF THE TEXT