

PACKAGE LEAFLET: INFORMATION FOR THE USER
Toilax Micro Enema 10mg/5ml Rectal Suspension
(bisacodyl)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- This medicine is for short term use only.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Toilax is and what it is used for
2. What you need to know before you use Toilax
3. How to use Toilax
4. Possible side effects
5. How to store Toilax
6. Contents of the pack and other information

1. WHAT TOILAX IS AND WHAT IT IS USED FOR

Toilax Micro Enema contains bisacodyl. It belongs to a group of medicines called laxatives, which are used to treat constipation. Enemas are an injection of a liquid through the back passage (rectum) to induce bowel movement.

Toilax can be used when required to clear the back passage (rectum) and relieve constipation for short term use only. It may also be used to clear the back passage before operations or childbirth.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TOILAX

Do not use Toilax if you:

- have ever used Toilax or any other enemas before and have had a bad reaction to them
- are hypersensitive (allergic) to any of the ingredients in Toilax
- suffer from severe abdominal or stomach pain
- have been told by a doctor that you have a condition called Ileus (swelling of the intestines when the bowel muscles have stopped working)
- are dehydrated
- are breast-feeding (please refer to section 'pregnancy and breast-feeding')
- suffer from ulcers, haemorrhoids, or inflammation in or around the back passage (rectum).

Warnings and Precautions

Talk to your doctor or pharmacist before using Toilax if any of the following applies to you:

- if you intend to use Toilax in a child under 10 years old (please refer to section 'children')
- if you have suffered continual constipation over a long period of time
- if you experience dizziness, loss of consciousness or fainting (syncope) as there have been some reports of this while using Toilax (please refer to section 4 Possible Side Effects).

Children

Toilax should only be used in Children under 10 years old if recommended by a doctor.

Other medicines and Toilax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular tell your doctor or pharmacist if you are taking any of the following:

- diuretics (water tablets)
- medicines to treat heart problems such as digoxin
- steroids such as hydrocortisone, fludrocortisone or cortisone.

The use of these medicines with Toilax may increase the imbalance of the levels of electrolyte (changes in the salt levels in the body).

Pregnancy and breast-feeding

Ask your doctor for advice before using Toilax if you are pregnant, planning to become pregnant or if you think you may be pregnant. Your doctor will decide if the benefits outweigh the risks.

You should not use Toilax if you are breast-feeding.

Driving and using machines

Toilax can cause dizziness and fainting. Do not drive or use machinery if you experience dizziness while taking this medicine.

Excipients

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

Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW TO USE TOILAX

Always use this medicine exactly as your pharmacist or doctor has told you. Check with your pharmacist or doctor if you are not sure.

The dosages described below refer to one administration per day for short term use only. Long term use is not recommended.

Adults and children over 10 years old:

Constipation: The usual dose is the contents of 1 micro enema applied to the rectum for immediate effect.

Preparation for operations: Only to be used under medical supervision. The usual dose is the contents of 1 micro enema on the morning of the operation. You may be prescribed some other laxative tablets to take on the day before the operation.

Children aged 10 years and younger:

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

Constipation (Children 2 to 10 years):

Only to be used if recommended by a doctor. The recommended dose is half a micro enema applied to the rectum for immediate effect.

Preparation for operations (Children 4 to 10 years):

Only to be used under medical supervision. The recommended dose is half a micro enema applied to the rectum on the morning of the operation. Your child may be prescribed some other laxative tablets to take on the day before the operation.

Older people:

Dosage as for adults. A dose of a half micro enema may be sufficient. Older people may need assistance to use this medicinal product.

The enema is for single use only. Please read the instructions carefully as they explain how to get the best effect from Toilax:

Instructions for using Toilax

1. Toilax should be stored in the refrigerator (from 2 to 8°C). Make sure the enema is at room temperature before use.

2. Twist off the end of the applicator. Gently squeeze the applicator to release a small amount of the Toilax suspension. Use this to lubricate the nozzle, by spreading along the stem of the nozzle.

3. Insert the nozzle into the rectum (back passage), as with a thermometer when taking a temperature.

4. Gently squeeze the applicator to deliver the medicine.

5. Slowly remove the applicator whilst it is still compressed.

6. Discard the enema container after use, even if you have only used half the contents.

7. Toilax micro enema normally works within 15 to 30 minutes but it can take up to 60 minutes.

Additional Instructions for use in children.

Toilax requires to be administered to children and the following additional instructions should be followed:

- it is easier to administer this medicine if the child is lying down before inserting the applicator.
- the applicator nozzle must not be inserted to more than half its length.

If you swallow Toilax

If you accidentally swallow the suspension, **contact your doctor or pharmacist, or go to your hospital emergency department.**

If you use more Toilax than you should

If you accidentally use too much Toilax, contact your doctor or pharmacist, or go to your hospital emergency department.

Overdosage with Toilax is likely to cause abdominal (stomach) cramps and diarrhoea, and can upset the body's electrolyte balance.

Excessive and prolonged use is dangerous and may result in:

- severe diarrhoea leading to complications such as low levels of salts in your blood (which can cause muscle weakness, twitching or abnormal heart rhythm), dehydration, poor absorption of nutrients from the digestive system
- constipation caused by over use of laxatives
- addiction to laxatives
- prolonged constipation or very slow digestive transit (chronic constipation) and loss of bowel function.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If the following happens stop using this medicine and seek medical advice immediately:

- Allergic reactions such as anaphylaxis and angioedema (swelling of the face, lips, tongue and/or throat), which may cause difficulty in swallowing and/or breathing, or result in a collapse.
- vomiting
- mild short-lived rash or itching

These side effects occur rarely.

Other side effects are:

Common (may affect up to 1 in 10 people):

- feeling sick (nausea)
- cramping and stomach pain.

Uncommon (may affect up to 1 in 100 people):

- irritation, pain, bleeding and mild inflammation in the back passage.

Not known (frequency cannot be estimated from the available data):

- Dizziness and/or loss of consciousness or fainting (syncope)
- blood in the stool (haematochezia).
- Colitis (inflammation of the inner lining of the colon)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Website: www.hpra.ie or e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TOILAX

- Keep this medicine out of the sight and reach of children.
- Store the medicine in its original container.
- Store in a refrigerator (2°C – 8°C). Keep the applicators in the outer carton, in order to protect from light.
- Do not use Toilax after the expiry date which is stated on the label or carton after 'Exp date'. The expiry date refers to the last day of that month.
- Toilax micro enema is for a single use only, any partly used enema containers should be discarded immediately after use.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Toilax contains

- The active substance is bisacodyl. Each millilitre (ml) of the suspension contains 2 mg of bisacodyl.
- Each applicator contains 5 ml of suspension equivalent to 10 mg of bisacodyl.
- The other ingredients are purified water, macrogol 3000, macrogol 4000, macrogol 400, citric acid monohydrate and sodium citrate.

What Toilax looks like and contents of the pack

Toilax is a white/grey suspension which is presented in a plastic applicator with a long nozzle. Toilax is available in cartons of 5 or 50 single dose units.

Marketing Authorisation Holder

Orion Corporation
Orionintie 1, FIN-02200 Espoo
Finland

Manufacturer

Orion Corporation
Orion Pharma, Kuopio, Finland

Orion Corporation
Orion Pharma, Salo, Finland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Orion Pharma (Ireland) Limited, c/o Allphar Services Ltd, 4045 Kingswood Road, Citywest Business Park, Co Dublin.

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