

Unofficial translation of the German package leaflet

Package leaflet: Information for the user

Mediolax[®] Medice 10 mg gastro-resistant tablets

Active substance: Bisacodyl

For use in adults and children over 10 years.

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

Always take 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.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. What Mediolax[®] Medice is and what it is used for
2. What you need to know before you take Mediolax[®] Medice
3. How to take Mediolax[®] Medice
4. Possible side effects
5. How to store Mediolax[®] Medice
6. Contents of the pack and other information

1. What Mediolax[®] Medice is and what it is used for

Mediolax[®] Medice is a laxative from the triphenylmethane group.

For short-term use in the event of constipation, in diseases that require an easier bowel movements (defecation).

2. What you need to know before you take Mediolax[®] Medice

Do not take Mediolax[®] Medice:

- if you are allergic to bisacodyl or any of the other ingredients of this medicine (listed in section 6), or if you have bowel obstruction, or in children under 10 years.

Warnings and precautions

Talk to your doctor or pharmacist before taking Mediolax[®] Medice.

Particular caution is required with the use of this medicine in the event of constipation associated with other symptoms, such as abdominal pain, vomiting and fever, as these may be signs of serious illness (bowel obstruction, acute inflammation in the stomach). If you have symptoms such as these, do not take Mediolax[®] Medice or other medicines and seek medical advice immediately.

You should not take Mediolax[®] Medice if you have any illnesses associated with impaired fluid and electrolyte balance.

Note:

Laxatives should only be used on a short-term basis from the treatment of constipation. In general, treatment with Mediolax[®] Medice is only recommended if no change or inadequate response is achieved through dietary changes (increased fibre intake and adequate fluid intake) and lifestyle changes (adequate physical exercise).

Other medicines and Mediolax[®] Medice

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Mediolax[®] Medice may increase potassium loss caused by other medicines (e.g., diuretics). Sensitivity to cardiac glycosides may be increased due to potassium loss.

Mediolax[®] Medice with food and drink

Milk and substances which neutralise stomach acidity (antacids) should be consumed no earlier than half an hour after the use of Medirolax[®] Medice.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There are no reported cases of undesirable effects during pregnancy and breast-feeding. Controlled studies have not been performed.

Medirolax[®] Medice should not be used at high doses and for an extended period of time during pregnancy.

Medirolax[®] Medice should not be used during breast-feeding, as there is insufficient information about possible transition into breast milk.

Driving and using machines

No specific precautions are necessary.

Important information about some of the ingredients of Medirolax[®] Medice

This medicine contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Medirolax[®] Medice.

3. How to take Medirolax[®] Medice

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children over 10 years take 1 gastro-resistant tablet of Medirolax[®] Medice (equivalent to 10 mg bisacodyl).

The tablet must be swallowed whole with plenty of water, preferably in the evening or on an empty stomach in the morning. Taking a dose in the evening leads to emptying of the bowel after about 10 hours. Taking a dose in the morning on an empty stomach leads to emptying of the bowel after about 6 hours.

Without medical advice, Medirolax[®] Medice should only be used as a short-term treatment. In the event of chronic constipation, you should consult your doctor for advice.

Please talk to your doctor or pharmacist if you feel that the effect of this medicine is too strong or too weak.

If you take more Medirolax[®] Medice than you should

Taking a larger amount of this medicine may cause diarrhoea. If you have severe symptoms, ask your doctor for advice.

If you forget to take Medirolax[®] Medice

Do not take a double dose to make up for a forgotten dose.

If you stop taking Medirolax[®] Medice

There are no known negative effects.

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.

Possible side effects:

Side effects are rare with short-term use.

Rare (affecting up to 1 in 1,000 patients treated)

- Flatulence
- Stomach pain
- Hypersensitivity reactions

Longer-term use of Medirolax[®] Medice very commonly leads to increased sluggishness of the bowels. Medirolax[®] Medice should therefore only be used as a short-term treatment.

Improper use of Mediolax[®] Medice (for too long and at doses that are too high) can very often result in increased loss of water, potassium and other salts. This can lead to disorders of heart function and muscular weakness, especially with the simultaneous use of medicines to increase urine output (diuretics) and hormones produced by the adrenal cortex (corticosteroids).

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 to the Bundesinstitut für Arzneimittel und Medizinprodukte [German Federal Office for Drugs and Medical Devices (BfArM)], Abt. Pharmakovigilanz [Pharmacovigilance Department], Kurt-Georg-Kiesinger Allee 3, 53175 Bonn, website: <http://www.bfarm.de>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mediolax[®] Medice

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton after "Expiry date". The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mediolax[®] Medice contains

The active substance is bisacodyl.
1 gastro-resistant tablet contains 10 mg bisacodyl

The other ingredients are: Microcrystalline cellulose, sorbitol (Ph. Eur.), sodium starch glycolate (type A) (Ph. Eur.), magnesium stearate (Ph. Eur.), methacrylic acid-ethyl acrylate copolymer (1: 1) (Ph. Eur.), polysorbate 80, sodium lauryl sulphate, talc, macrogol 6000, titanium dioxide (E171), iron(III) oxide-hydroxide (E172), brilliant blue FCF (E133), carmellose sodium, sodium hydroxide

What Mediolax[®] Medice looks like and contents of the pack

Round, green gastro-resistant tablets

1 pack contains 50 gastro-resistant tablets

Pharmaceutical company and manufacturer

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This leaflet was last revised in July 2016.