

Bisacodyl A1WA®

5 mg sugar-coated tablets

Bisacodyl



For use in children aged over 2 years, adolescents and adults.

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

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1. What Bisacodyl A1WA® 5 mg is and what it is used for

Bisacodyl A1WA® 5 mg is a laxative.

Bisacodyl A1WA® 5 mg is used for the short-term relief of constipation, for diseases that require easier emptying of the bowel, as well as for emptying of the bowel for treatment measures and measures for the detection of diseases (therapeutic and diagnostic interventions) of the bowel. As with other laxatives, Bisacodyl A1WA® 5 mg should not be taken daily or for an extended period of time without medical evaluation of the cause of constipation.

2. What you need to know before you take Bisacodyl A1WA® 5 mg

Do not use Bisacodyl A1WA® 5 mg

- if you are allergic to bisacodyl, the dye Sunset Yellow, or any of the other ingredients of this medicine (listed in section 6).
- for symptoms such as abdominal pain, nausea, vomiting or fever. These could be signs of a serious disease (intestinal constriction with aggravated intestinal passage, intestinal obstruction, acute inflammation in the abdominal area, acute abdominal pains requiring surgical treatment, such as appendicitis). Consult a doctor straight away if you experience any of these symptoms.
- in the case of a rare congenital intolerance to glucose, lactose or sucrose (sugar) (see below, section "Important information about some of the ingredients of Bisacodyl A1WA® 5 mg").
- if the patient is a child under the age of 2 years.

In disorders associated with disturbances of the water and mineral salt balance (e.g. considerable lack of body fluids), you should not take Bisacodyl A1WA® 5 mg.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bisacodyl A1WA® 5 mg.

Laxatives should only be taken short-term without medical evaluation. In the case of chronic constipation you should consult your doctor before taking this medicine.

Increased fluid loss can lead to excessive loss of body water (dehydration). Under certain circumstances (e.g. in patients with impaired kidney function or elderly people), this can have harmful effects on health. In such cases, Bisacodyl A1WA® 5 mg should be discontinued and continued only under medical supervision.

Patients have reported the presence of blood in the stool, which was generally described as weak and stopped on its own. In patients who have taken Bisacodyl A1WA® 5 mg, dizzy spells or brief attacks of unconsciousness (syncope) have been reported. According to the corresponding case reports, these are presumably syncopes that either originate from the laxative process itself, from pressing, or from circulatory reactions due to abdominal pains.

Children

Bisacodyl A1WA® 5 mg must not be used in children under the age of 2 years. Bisacodyl A1WA® 5 mg should only be used in children on doctor's instructions.

Other medicines and Bisacodyl A1WA® 5 mg

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

Neutralising stomach medications (antacids)

To prevent premature release of the active substance of Bisacodyl A1WA® 5 mg, neutralising stomach medications (antacids) should not be taken at the same time as Bisacodyl A1WA® 5 mg. If you need a stomach medicine, take it at least half an hour after Bisacodyl A1WA® 5 mg.

Diuretic agents, hormones of the adrenal cortex

The simultaneous use of water tablets (diuretics) or adrenal cortex hormones (corticosteroids) can increase the risk of electrolyte imbalances in the case of excessive use of Bisacodyl A1WA® 5 mg.

Cardiotonic agents

Sensitivity to certain medicines for strengthening cardiac function (cardiac glycosides) may be increased by electrolyte imbalances due to excessive use.

Bisacodyl A1WA® 5 mg with food, drink and alcohol

Bisacodyl A1WA® 5 mg should not be taken with milk to prevent the active substance being released prematurely.

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.

Pregnancy

Since the introduction of bisacodyl in 1952, no undesirable or harmful effects during pregnancy have become known. Studies on the use during pregnancy have not been conducted. Therefore, Bisacodyl A1WA® 5 mg, like all medicines, should only be used during pregnancy after consulting your doctor.

Breast-feeding

It has been shown that the active substance is not excreted in human milk. Bisacodyl A1WA® 5 mg can therefore be used during breast-feeding.

Driving and using machines

No studies have been conducted on the effects on driving and the ability to use machines. Please note that side effects may occur which could theoretically impair your ability to drive and use machines.

Important information about some of the ingredients of Bisacodyl A1WA® 5 mg

Bisacodyl A1WA® 5 mg contains glucose (dextrose), lactose (milk sugar) and sucrose (sugar).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Bisacodyl A1WA® 5 mg.

3. How to take Bisacodyl A1WA® 5 mg

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.

Dosage

Unless otherwise directed by the doctor, the usual dose is:

- for adults and children over 10 years of age: 1 - 2 Bisacodyl A1WA® 5 mg (equivalent to 5 - 10 mg bisacodyl) once in the evening;
- for children from 2 to 10 years: 1 Bisacodyl A1WA® 5 mg (equivalent to 5 mg bisacodyl) once in the evening.

It is recommended to start with the lowest dose. The dose can be adjusted up to the maximum recommended dose to enable regular bowel movements. The maximum daily dose of 1 - 2 gastro-resistant tablets (for adults and children from 10 years of age) or 1 gastro-resistant tablet (for children from 2 to 10 years of age) should not be exceeded.

Swallow Bisacodyl A1WA® 5 mg whole with sufficient liquid (preferably a glass of water but not with milk).

Ingestion will lead to emptying of the bowels after approximately 6 - 12 hours. To empty the bowels for treatment measures and measures to detect diseases (therapeutic and diagnostic interventions) in the bowel as well as for diseases that require an easier emptying of the bowel, the medication is to be taken according to the doctor's instructions.

As a rule, Bisacodyl A1WA® 5 mg is taken only once. Bisacodyl A1WA® 5 mg can be taken again for recurrent symptoms. Bisacodyl A1WA® 5 mg should not be taken daily continuously or for extended periods of time without evaluation of the cause of blockage (constipation).

If you take more Bisacodyl A1WA® 5 mg than you should

Overdosage can lead to diarrhoea and abdominal cramps with high losses of fluid, potassium and other mineral salts. If you have severe symptoms, ask your doctor for advice.

Treatment depends on the prevailing symptoms. If necessary, the loss of liquid and salt (especially potassium) must be compensated.

NB

It is generally known that laxatives (e.g. Bisacodyl A1WA® 5 mg) can cause chronic diarrhoea, abdominal pain, lowered potassium levels, excessive secretion of aldosterone and kidney stones in chronic overdose. In connection with chronic laxative abuse, damage to the kidney tissue, metabolism-induced increase in the concentrations of alkaline substances in the blood and muscle weakness caused by lowered potassium levels have also been reported.

If you forget to take Bisacodyl A1WA® 5 mg

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

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. The most commonly reported side effects during treatment are abdominal pain and diarrhoea.

The following frequency convention is used in the evaluation of side effects:

Very common: more than 1 in 10 people

Common: 1 to 10 in 100 people

Uncommon: 1 to 10 in 1,000 people

Rare: 1 to 10 in 10,000 people

Very rare: less than 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

Possible side effects

Immune system

Rare: hypersensitivity reactions

Not known: severe allergic immediate reaction, swelling of skin and mucosa

Metabolic disorders

Not known: loss of water

Gastrointestinal tract

Common: abdominal cramps, abdominal pain, diarrhoea, nausea

Rare: vomiting, blood in stool, abdominal symptoms, rectal symptoms

Not known: inflammation of the colon

Nervous system

Uncommon: dizziness

Not known: brief unconsciousness (syncope)

These are presumably circulatory reactions due to constipation-related abdominal pain or the discharge process itself (see also section 2 under "Take special care with Bisacodyl A1WA® 5 mg").

Other possible side effects

Sunset Yellow can cause allergic reactions.

Inappropriate use of Bisacodyl A1WA® 5 mg (too long treatment period and too high doses) can lead to loss of water, potassium and other electrolytes. This can lead to cardiac dysfunction and muscle weakness, especially when taking water tablets (diuretics) and hormones of the adrenal cortex (corticosteroids) at the same time. Sensitivity to certain medicines for strengthening cardiac function (cardiac glycosides) may be increased.

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

5. How to store Bisacodyl A1WA® 5 mg

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 carton and the blister after "EXP". The expiry date refers to the last day of that month. Do not store above 25 °C.

Do not throw away any medicines via wastewater. 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 Bisacodyl A1WA® 5 mg contains

The active substance is bisacodyl.

Each gastro-resistant tablet (sugar-coated tablet) contains 5 mg bisacodyl.

The other ingredients are:

Tablet core: lactose monohydrate, icing sugar, maize starch (native), povidone 25, colloidal anhydrous silica, modified starch, talcum (ex magnesia), magnesium stearate (Ph. Eur., vegetable), **Tablet coating:** methacrylic acid, talcum (ex magnesia), castor oil (refined Ph. Eur.), granulated sugar, gum arabic, glucose syrup, calcium carbonate, titanium dioxide, pyrogenic silicon dioxide, maize starch, aluminium silicate, povidone 25, polyethylene glycol 6000, Cremophor RH 4100, Quinoline Yellow (E104), iron oxide (E172), Sunset Yellow (E110), montan glycol wax.

What Bisacodyl A1WA® 5 mg looks like and contents of the pack

Yellow, glossy, coated, gastro-resistant tablets (sugar-coated tablets) for oral use. Bisacodyl A1WA® 5 mg is available in packs of 20, 40 and 100 gastro-resistant tablets (sugar-coated tablets).

Marketing Authorisation Holder

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Dear patient,

Nearly everyone suffers from constipation at some time in their life. The reasons for this can vary considerably by individual. In the following you will find some advice on the topic of constipation and how to use Bisacodyl A1WA® 5 mg.

When do we speak of constipation?

Every person has his or her own bowel rhythm: at three times a week, up to three times a day, we speak of a normal frequency of bowel movement.

Important: daily bowel movements are not absolutely necessary. From a medical point of view, constipation is referred to as bowel movements less frequently than three times a week, where strong pressing is required and/or the stool consistency is hard and dry. Often one feels that the bowels have not been emptied completely.

What are the causes of constipation?

Constipation occurs when the natural movement of the colon slows down or is insufficient to eliminate the digested food pulp. This problem can have a number of reasons:

- hormonal influences or changes (e.g. pregnancy, imminent menstrual bleeding, menopause)
- stress
- changes in eating or lifestyle habits (e.g. on travels)
- certain diseases (for example, diabetes mellitus or Parkinson's disease)
- certain medications (for example, antidepressants, strong painkillers, iron preparations)
- at increasing age

How does Bisacodyl A1WA® 5 mg work?

Bisacodyl A1WA® 5 mg contains the active substance bisacodyl, which has been tried and tested for over 60 years. Each Bisacodyl A1WA® 5 mg gastro-resistant tablet contains a special coating that releases the active substance only when it reaches the large intestine - in other words, only at the actual site of constipation. There, bisacodyl stimulates the natural movement of the intestine and thus relieves constipation.

NB:

After taking Bisacodyl A1WA® 5 mg, give your intestine some time to refill. Depending on the composition and quantity of food, this can take several days until the rectum is filled sufficiently to allow natural stool pressure again. Please do not forget: daily bowel movements are not absolutely necessary!

How do I establish my personal dosage?

When using Bisacodyl A1WA® 5 mg for the first time, we recommend starting with one tablet.

The personally correct dosage of Bisacodyl A1WA® 5 mg is the lowest dosage required to obtain a soft, formed stool:

- for adults and children over 10 years of age: 1 - 2 Bisacodyl A1WA® 5 mg (equivalent to 5 - 10 mg bisacodyl) once.
- for children from 2 to 10 years: 1 Bisacodyl A1WA® 5 mg (equivalent to 5 mg bisacodyl) once.