

Package leaflet: Information for the user
BISACODYL 5 mg TABLETS

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

This medicine is available without prescription. You need to take Bisacodyl 5 mg Tablets as instructed in this leaflet to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your pharmacist or doctor if your symptoms worsen or do not improve after five days treatment.
- 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

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1. What Bisacodyl 5 mg Tablets are and what they are used for

Bisacodyl 5 mg Tablets are used for the short-term relief of occasional constipation. Bisacodyl 5 mg Tablets contains bisacodyl and belongs to a group of medicines known as stimulant laxatives, which increase bowel movements. This medicine does not help with weight loss.

What is constipation?

Normal and regular bowel movement is important for most people. However, what is “normal and regular” varies from person to person. Some may have a bowel movement every day, others less often. Whatever it is like for you, it is best that your bowel movement has a regular pattern.

- Constipation is an occasional problem for some people.
- For others, it may happen more often.
- It happens when the normal muscle actions in the bowel (large intestine) slow down. This can mean that material is not easily eliminated from the body.

The cause of constipation is often not known. It can be associated with:

- Sudden change of diet
- A diet with not enough fibre
- Not drinking enough fluids
- Loss of ‘tone’ of the bowel muscles in older people
- Pregnancy
- Medicines such as morphine or codeine
- Having to stay in bed for a long time
- Lack of exercise

Whatever the cause, constipation can be uncomfortable. It may make you feel bloated and heavy or generally “off colour”. Sometimes it causes headaches.

It is recommended to use changes in diet and bulk forming medicines to control constipation before using this medicine.

These healthy tips are recommended to try to prevent constipation happening:

- Eat a balanced diet including fresh fruit and vegetables
- Drink enough water so that you do not become dehydrated
- Keep up your exercise and stay fit
- Make time to empty your bowels when your body tells you

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

Do not take Bisacodyl 5 mg Tablets if you:

- are allergic to bisacodyl (hypersensitive) or any of the other ingredients in the medicine (listed in Section 6).
- are intolerant to or cannot digest some sugars (as the tablet contains a small amount of lactose monohydrate)
- have severe dehydration
- have a bowel condition called “ileus” (blockage in the intestine)
- have a serious abdominal condition such as appendicitis
- have severe abdominal pain with nausea and vomiting
- have a blocked bowel (intestinal obstruction)
- have inflammation of the bowel (small or large intestine)

Do not take this medicine if any of the above applies to you. Do not use in children under the age of 12 years. If you are not sure, talk to your doctor or pharmacist before taking Bisacodyl 5 mg Tablets.

Warnings and precautions

As with all laxatives, Bisacodyl 5 mg Tablets should not be taken every day for more than five days. If you need laxatives every day, or if you have abdominal pain which does not go away, you should see your doctor.

Does this help with weight loss?

Stimulant laxatives (including bisacodyl) do not help with weight loss. They do not reduce the absorption of calories or nutrients. They can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

Overuse of laxatives may damage your health by:

- Causing disturbances of electrolyte and mineral balances. Sodium, potassium, magnesium and phosphorus are electrolytes and minerals that are present in very specific amounts necessary for proper functioning of the nerves and muscles, including those of the colon and heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs.
- Severe dehydration may cause tremors, weakness, blurry vision, fainting, kidney damage, and, in extreme cases, death. Dehydration often requires medical treatment.
- Overuse of laxatives must be avoided as it may harm the intestinal function.

Other medicines and Bisacodyl 5 mg Tablets

Please tell your pharmacist or doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Bisacodyl 5 mg Tablets can affect the way some other medicines work. Also, some other medicines can affect the way Bisacodyl 5 mg Tablets work.

In particular, tell your doctor or pharmacist if you are taking:

- Water tablets (diuretics) such as bendrofluazide or furosemide (frusemide).
- Steroid medicines such as prednisolone.
- Other laxative medicines.

If you are not sure if any of the above applies to you, talk to your pharmacist or doctor before taking Bisacodyl 5 mg Tablets.

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.

Driving and using machines

Some people may feel dizzy or faint while taking this medicine. If this happens to you, wait until these feelings go away before driving or using machines.

Bisacodyl 5 mg Tablets contain lactose monohydrate and tartrazine (E102)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Bisacodyl 5 mg Tablets also contain tartrazine (E102), which may cause allergic reactions.

3. How to take Bisacodyl 5 mg Tablets

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.

Dose for oral tablets

For constipation: Adults (including the elderly) and children over the age of 12 years:

1 to 2 tablets at night.

- Swallow the tablets **whole with water. Do not crush or chew the tablets.**
- Milk, antacids or proton-pump inhibitors (medicines which reduce stomach acid) should not be taken within one hour before or after taking Bisacodyl 5 mg Tablets. This is because they will stop the Bisacodyl 5 mg Tablets from working properly.

If you have not taken Bisacodyl 5 mg Tablets before, start with one tablet and increase to two if necessary. When your bowel regularity has returned to normal, the dose can usually be stopped.

Length of treatment

These tablets should **not be used every day for more than 5 days**. If you need laxatives every day, then you should see your doctor to find the cause of your constipation.

Overuse can be harmful.

If you take more Bisacodyl 5 mg Tablets than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take your medicine and this leaflet with you. This is so the doctor knows what you have taken.

It may be harmful to:

- Take too many Bisacodyl 5 mg Tablets
- Take Bisacodyl 5 mg Tablets for too long.

This is because taking too much for too long may lead to:

- A 'lazy bowel', where the muscle in the bowel becomes too relaxed. This means that bowel emptying happens less often. This can lead to long-term constipation.
- Imbalance of fluid and salts in the body. This can affect the tightness of muscles such as those in the bowel. It can also affect the salts in the blood.
- Low levels of potassium in the blood (called 'hypo-kalaemia'). This can make you tired, dizzy, make your muscles weak and cause an uneven heart beat.
- Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean you cannot pass enough urine.

If you forget to take your medicine

If you forget to take your tablets, just take the next dose at the usual time, DO NOT take a double dose to make up for the forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any of the following side effects, please stop taking the medicine and see your doctor straight away:

Rare side effects (affect less than 1 in 1000 people)

- Severe allergic reactions which may cause swelling of the face or throat and difficulty in breathing or dizziness.
If you have a severe allergic reaction, stop taking this medicine and see a doctor straight away.
- Colitis (inflammation of the large intestine which causes abdominal pain and diarrhoea)
- Dehydration
- Allergic reactions which may cause a skin rash
- Fainting

Uncommon side effects (affect less than 1 in 100 people)

- Blood in the stools
- Vomiting
- Abdominal discomfort
- Discomfort inside and around the back passage
- Dizziness

Common side effects (affect less than 1 in 10 people)

- Abdominal cramps or pain
- Diarrhoea
- Nausea

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bisacodyl 5 mg Tablets

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 on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture.

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 Bisacodyl 5 mg Tablets contain**

The active substance is bisacodyl.

Bisacodyl 5 mg gastro-resistant tablets contain 5 mg of bisacodyl.

The other ingredients are lactose monohydrate, maize starch, magnesium stearate, hypromellose, triacetin, talc, methacrylic acid and ethyl acrylate copolymer, triethyl citrate, titanium dioxide, colloidal anhydrous silica, sodium bicarbonate, sodium lauryl sulfate, macrogol and tartrazine (E102).

What Bisacodyl 5 mg Tablets look like and the contents of the pack

Bisacodyl 5 mg Tablets are yellow coloured, circular, biconvex, film coated tablets plain on both sides.

They are available in foil blister packs of 40, 60 tablets and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK

Manufacturer

Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK

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