### PACKAGE LEAFLET: INFORMATION FOR THE USER Bisacodyl 5mg Laxative Tablets 12+ 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 have 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.

#### What is in this leaflet:

- 1. What Bisacodyl 5mg Laxative Tablets are and what they are used for
- 2. What you need to know before you take Bisacodyl 5mg Laxative Tablets 12+ years
- 3. How to take Bisacodyl 5mg Laxative Tablets 12+ years
- 4. Possible side effects
- 5. How to store Bisacodyl 5mg Laxative Tablets 12+ years
- 6. Contents of the pack and other information

## 1. What Bisacodyl 5mg Laxative Tablets 12+ years are and what they are used for

Bisacodyl 5mg Laxative Tablets 12+ years are used for the short-term relief of occasional constipation. Bisacodyl 5mg Laxative Tablets 12+ years contain bisacodyl and belong 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 5mg Laxative Tablets 12+ years

### Do not take Bisacodyl 5mg Laxative Tablets 12+ years if:

- You are allergic (hypersensitive) to bisacodyl or any of the other ingredients in the product (listed in Section 6: Contents of the pack and other information)
- You are intolerant to or cannot digest some sugars (as the tablet contains a small amount of lactose and sucrose)
- You have severe dehydration
- You have a bowel condition called "ileus" (blockage in the intestine)
- You have a serious abdominal condition such as appendicitis
- You have severe abdominal pain with nausea and vomiting
- You have a blocked bowel (intestinal obstruction)
- You 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 pharmacist or doctor before taking this medicine.

### 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 5mg Laxative Tablets 12+ years

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Bisacodyl 5mg Laxative Tablets 12+ years can affect the way some other medicines work. Also, some other medicines can affect the way Bisacodyl 5mg Laxative Tablets 12+ years 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 5mg Laxative Tablets 12+ years.

### Pregnancy and breast feeding

Talk to your pharmacist or doctor before taking Bisacodyl 5mg Laxative Tablets 12+ years ifyou are pregnant, planning to become pregnant or are breast feeding.

### 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 5mg Laxative Tablets 12+ years contain lactose and sucrose

The tablets contain a small amount of lactose and sucrose in each tablet. Patients with rare hereditary problems of fructose intolerance, galactose intolerance, total lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not use this medicine. If you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. How to take Bisacodyl 5mg Laxative Tablets 12+ years

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

For constipation: Adults (including the elderly) and children over 12 years: 1 to 2 tablets at night.

- Swallow the tablets whole with water. The tablets should not be chewed or crushed.
- Milk, antacids or proton pump inhibitors (medicines which reduce stomach acid) should not
  be taken within one hour before or after taking Bisacodyl 5mg Laxative Tablets 12+ years.
  This is because they will stop the Bisacodyl 5mg Laxative Tablets 12+ years from working
  properly.

If you have not taken Bisacodyl 5mg Laxative Tablets 12+ years 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 Laxative Tablets 12+ years than you should It may be harmful to:

- Take too many Bisacodyl 5mg Laxative Tablets 12+ years
- Take Bisacodyl 5mg Laxative Tablets 12+ years for too long

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

- 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 'hypokalaemia'). 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 take more of this medicine than you should, talk to a doctor or go to a hospital straight

away. Take the medicine pack with you; this is so the doctor knows what you have taken.

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

### 4. Possible side effects

Like all medicines, Bisacodyl 5mg Laxative Tablets 12+ years can cause side effects, although not everybody gets them. If you experience any of the following side effects, please stop taking the medicines 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 or pharmacist. 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 5mg Laxative Tablets 12+ years

- Keep this medicine out of the sight and reach of children
- Do not take Bisacodyl 5mg Laxative Tablets 12+ years after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month
- Do not store above 25°C
- Keep the blister within the outer carton
- 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 5mg Laxative 12+ years Tablets contain

The active ingredient (the ingredient which makes this medicine work) is Bisacodyl. Each tablet contains 5mg of Bisacodyl.

The tablets also contain: lactose, maize starch, cellulose acetate phthalate, diethyl phthalate, sucrose, povidone, magnesium stearate, pregelatinised maize starch, talc, E171 (titanium dioxide) and E104 (quinoline yellow).

### What your tablets look like and the contents of the pack

Bisacodyl 5mg Laxative Tablets 12+ years are round, yellow, sugar-coated tablets. They are packed in cartons containing blister strips of 8, 10, 20, 28, 30, 40, 50, 56, 60, 84 or 100 tablets

Not all pack sizes may be marketed.

If you want to know more about your medicine, ask your doctor or pharmacist who can give you more information.

## Marketing authorisation holder and manufacturer

Dr. Reddy's Laboratories (UK) Ltd. 410 Cambridge Science Park, Milton Road Cambridge, CB4 0PE, United Kingdom

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