

PACKAGE LEAFLET: INFORMATION LEAFLET FOR THE USER

# Bisacodyl 5mg Gastro-resistant Tablets

(Bisacodyl)

**Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. You still need to take Bisacodyl 5mg gastro-resistant 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 doctor or pharmacist if your symptoms worsen or do not improve after five days of treatment.
- If a side effect occurs and gets troublesome, or seems serious to you, or if you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. **What Bisacodyl is and what it is used for**
2. **Before you take Bisacodyl**
3. **How to take Bisacodyl**
4. **Possible side effects**
5. **How to store Bisacodyl**
6. **Further information**

## 1. WHAT BISACODYL IS AND WHAT IT IS USED FOR

- Bisacodyl 5mg Gastro-resistant tablets contain a medicine called bisacodyl. This belongs to a group of medicines called laxatives.
- Bisacodyl is used for relief of constipation.
- Bisacodyl can also be used in a hospital to empty a person's bowel before child birth, surgery or radiological investigations.
- Bisacodyl gently stimulate the muscles of the bowel (large intestine). This brings predictable, overnight relief from constipation, helping to return the body to its natural rhythm.
- Bisacodyl 5mg Gastro-resistant Tablets have a special coating that helps to ensure the medicine works only where it is needed.

Bisacodyl 5mg Gastro-resistant Tablets do 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
- Loss of 'tone' in 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.

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 bowel when your body tells you.

## 2. BEFORE YOU TAKE BISACODYL

### Do not take Bisacodyl if:

- You are allergic (hypersensitive) to bisacodyl or any of the other ingredients in the product tablets. (listed in Section 6: Further 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. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

### Taking other medicines

Please tell your doctor or pharmacist 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 can affect the way some other medicines work. Also, some other medicines can affect the way Bisacodyl works.

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

- water tablets (diuretics) such as bendrofluzide or furosemide (frusemide)
- steroid medicines such as prednisolone
- indigestion remedies

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

### Pregnancy and breast feeding

Talk to your doctor or pharmacist before taking Bisacodyl if you are pregnant, planning to become pregnant or are breast feeding. It is not advised to take this medicine whilst 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.

### Important information about some of the ingredients of Bisacodyl

This medicine contains lactose (a milk sugar) and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. The tablets also contain Tartrazine (E102) which may cause allergic reactions.

## 3. HOW TO TAKE BISACODYL

If this medicine is from your doctor or pharmacist, do exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or you are not sure, ask your doctor or pharmacist.

**As with all laxatives, Bisacodyl 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.**

### Taking this medicine:

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

### How much to take

#### *Adults and children over 10 years old*

- Take one or two tablets (5 to 10 mg) daily before bedtime.
- If you have not taken Bisacodyl 5mg Gastro-resistant 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.

#### *Children aged between 4 and 10 years*

Bisacodyl 5mg Gastro-resistant Tablets should only be given to children between the ages of 4 and 10 if recommended by a doctor. The usual dose for children is:

- one tablet (5 mg) daily before bedtime.

#### *Children under 4 years*

Bisacodyl 5mg Gastro-resistant Tablets are not recommended for children under 4 years.

#### *Elderly patients:*

If you are elderly, you may be prescribed a lower dose.

### If you take more Bisacodyl than you should

It may be harmful to:

- take too much bisacodyl
- take bisacodyl 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 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 forget to take Bisacodyl

If you have forgotten to take your tablet at night, wait for the next dose and continue as before. Do not take any more tablets in one day than your doctor has prescribed. Do not take a double dose to make up for a missed dose.

If you feel that the effect of your medicine is too strong or too weak, talk to your doctor or pharmacist.

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

## 4. POSSIBLE SIDE EFFECTS

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

### Stop taking the tablets and tell your doctor or pharmacist immediately if you experience any of the following rare effects:

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

- A severe or itchy skin rash
- Swelling of the hands, face, lips or tongue
- Difficulty breathing or wheezing, dizziness
- Colitis (inflammation of the large intestine which causes abdominal pain and diarrhea)
- Dehydration
- Fainting

### These are all possible signs of a severe allergic reaction.

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

**If any of the side effects gets troublesome or seems serious to you, or if you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

### 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom** Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

## 5. HOW TO STORE BISACODYL

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

Do not use Bisacodyl after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original container. Keep the container tightly closed (for polypropylene containers only).

Do not use Bisacodyl if you notice any deterioration or damage to the outer packaging

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. FURTHER INFORMATION

### What Bisacodyl contains

Each tablet contains 5 mg of bisacodyl as the active ingredient.

The other ingredients are: **Core Tablet:** Lactose monohydrate, Liquid paraffin, Maize starch and Magnesium stearate. **Enteric Coating:** Methacrylic acid Co-Polymer Ethyl Acrylate Co Polymer (1:1) dispersion 30% material, Macrogol 3350, Talc and Simethicone PD30. **Sugar Coat:** Povidone K30, Talc, Kaolin light and Sucrose. **Colour Coat:** Titanium dioxide (E171) and Tartrazine lake (E102). **Polishing:** Carnauba wax.

### What Bisacodyl looks like and contents of the pack

Bisacodyl are yellow shiny biconvex sugar coated gastro resistant tablets.

Bisacodyl 5mg, gastro-resistant tablets are available in blister packs (cartons) of 20, 60 and 100 tablets and in polypropylene containers of 500 and 1000 tablets.

**Marketing Authorisation Holder and Manufacturer:** Chanelle Medical, Loughrea, Co. Galway, Ireland.

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Client	Chanelle		Colours used:
Date	12.02.15		Black
Product	BISACODYL 5mg PIL		
Pack Code			
Scale / Size	1:1 / 156 x 348mm		
Software	Illustrator CS5		
Proof No	5		
Contact	Ray McDonnell		Minimum Text 8pt