

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Dulcolax 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 need to take DULCOLAX 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 a side effect occurs and gets troublesome, or seems serious to you, or if you experience any side effect not listed in this leaflet, please tell your pharmacist or doctor

### **In this leaflet:**

1. What DULCOLAX Tablets are and what they are used for
2. Before you take DULCOLAX Tablets
3. How to take DULCOLAX Tablets
4. Possible side effects
5. How to store DULCOLAX Tablets
6. Further information

### **1. WHAT DULCOLAX TABLETS ARE AND WHAT THEY ARE USED FOR**

- DULCOLAX Tablets contain a medicine called bisacodyl. This belongs to a group of medicines called laxatives
- DULCOLAX Tablets are used for relief of constipation
- This medicine does not help with weight loss
- DULCOLAX Tablets can also be used in a hospital to empty a person's bowel before child birth, surgery or radiological investigations
- DULCOLAX Tablets 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
- DULCOLAX Tablets are gastro-resistant tablets which have a special coating that helps to ensure the medicine works only where it is needed

### **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' 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.

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. BEFORE YOU TAKE DULCOLAX TABLETS**

### **Do not take DULCOLAX Tablets if:**

- You are allergic (hypersensitive) to bisacodyl or any of the other ingredients in the product (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 pharmacist or doctor before taking this medicine.

### **Taking other medicines**

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 DULCOLAX Tablets can affect the way some other medicines work. Also, some other medicines can affect the way DULCOLAX Tablets works.

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 DULCOLAX Tablets

### **Pregnancy and breast feeding**

Talk to your pharmacist or doctor before taking DULCOLAX Tablets if you 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.

#### **Dulcolax Tablets contain lactose and sucrose**

The tablets contain a small amount of lactose and sucrose in each tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

### **3. HOW TO TAKE DULCOLAX TABLETS**

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 pharmacist or doctor.

As with all laxatives, DULCOLAX 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.

#### **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 DULCOLAX Tablets. This is because they will stop the DULCOLAX Tablets from working properly

#### **How much to take**

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

- Take one or two tablets (5 or 10 mg) daily before bedtime
- If you have not taken DULCOLAX 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**

DULCOLAX 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**

DULCOLAX Tablets are not recommended for children under 4 years.

#### **If you take too many DULCOLAX Tablets**

It may be harmful to

- Take too many DULCOLAX Tablets or
- Take DULCOLAX Tablets 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 DULCOLAX 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 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, DULCOLAX Tablets can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

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

##### **Ireland**

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

##### **Malta**

ADR Reporting

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

#### **5. HOW TO STORE DULCOLAX TABLETS**

- Keep this medicine out of the sight and reach of children
- Do not take DULCOLAX Tablets 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 strip within the outer carton

- 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 DULCOLAX Tablets contain**

- Each tablet contains 5 mg of bisacodyl as the active ingredient
- The other ingredients are: lactose monohydrate, maize starch, sucrose (approximately 21 mg per tablet), glycerol, magnesium stearate, talc (E553b), acacia (powdered), white beeswax (E901), shellac (E904), carnauba wax (E903), titanium dioxide (E171), yellow iron oxide (E172), methacrylic acid-methyl methacrylate copolymer, castor oil and macrogol 6000

### **What DULCOLAX Tablets looks like and contents of the pack**

DULCOLAX Tablets are yellow. They are available in packs of 10, 20, 30, 40, 50, 60, 80 and 100. Not all pack sizes may be marketed.

### **The Marketing Authorisations are held by:**

#### **Ireland**

Opella Healthcare France SAS  
157 avenue Charles de Gaulle  
92200 Neuilly-sur-Seine, France.

#### **Malta**

Opella Healthcare France SAS  
157 avenue Charles de Gaulle  
92200 Neuilly-sur-Seine, France.

### **DULCOLAX Tablets are manufactured at:**

Delpharm Reims S.A.S.  
10 Rue Colonel Charbonneaux  
51100 Reims, France.

For any information about this medicine, please contact the distributor & local representative of the Marketing Authorisation Holder:

Clonmel Healthcare Ltd.,  
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