

Dulcolax[®]

Twelve Plus

5 mg Gastro-resistant Tablets
bisacodyl

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 Dulcolax Twelve Plus Tablets are and what they are used for
2. What you need to know before you take Dulcolax Twelve Plus Tablets
3. How to take Dulcolax Twelve Plus Tablets
4. Possible side effects
5. How to store Dulcolax Twelve Plus Tablets
6. Contents of the pack and other information

1. What Dulcolax Twelve Plus Tablets are and what they are used for

Dulcolax Twelve Plus Tablets are used for the short-term relief of occasional constipation. Dulcolax Twelve Plus Tablets 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 Dulcolax Twelve Plus Tablets

Do not take Dulcolax Twelve Plus Tablets 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 Dulcolax Twelve Plus Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Dulcolax Twelve Plus Tablets can affect the way some other medicines work. Also, some other medicines can affect the way Dulcolax Twelve Plus Tablets work.

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
- 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 Twelve Plus Tablets

Pregnancy and breast feeding

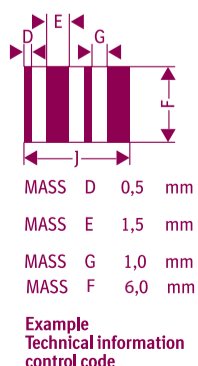
Talk to your pharmacist or doctor before taking Dulcolax Twelve Plus Tablets if you are pregnant, planning to become pregnant or are breast feeding.



SANOFI

320524-17

ADDITIONAL REQUIREMENT OF PACKAGING LINE	
Description :	PI DULCOLAX 5MG TABSC 40/60/100 M36 GB
Dimension :	160 x 290 mm
No. of code :	150
Ref. drawing :	PR32 Issue date of TD: 08/01/2020



pack2edit

Digital · Packaging · Development

SANOFI

File information

GMID code:	768942 / 768944 / 768945
Plant PM code:	1060029607
Second Plant PM code:	320524-17
Version of artwork:	V4
PM type:	PI
Market:	GB
Format:	160 x 290 mm
Issue date of artwork:	26/Feb/2020
Print colors:	Pan 357
Number of print colors:	1
Used font:	Bliss Pro
Min. font size:	8 pt
p2e number:	931097

Technical colors

Diecut-Legendcase	Free area	Glue points

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 Twelve Plus Tablets 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, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

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

3. How to take Dulcolax Twelve Plus Tablets

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 Dulcolax Twelve Plus Tablets. This is because they will stop the Dulcolax Twelve Plus Tablets from working properly

If you have not taken Dulcolax Twelve Plus 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 Dulcolax Twelve Plus Tablets than you should

It may be harmful to

- Take too many Dulcolax Twelve Plus Tablets or
- Take Dulcolax Twelve Plus 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 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 Twelve Plus Tablets 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 Dulcolax Twelve Plus Tablets

- Keep this medicine out of the sight and reach of children
- Do not take Dulcolax Twelve Plus 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 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 Dulcolax Twelve Plus 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 your tablets look like and the contents of the pack

Dulcolax Twelve Plus Tablets are yellow. They are packed in cartons containing blister strips. The cartons contain 40, 60 or 100 tablets. Not all pack sizes may be marketed.

The Marketing Authorisation is held by:

Sanofi, 410 Thames Valley Park Drive,
Reading, Berkshire,
RG6 1PT, United Kingdom.
Tel: 0845 372 7101
Email: uk-medicalinformation@sanofi.com

Dulcolax Twelve Plus Tablets are manufactured at:

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

This leaflet was revised in February 2020

® Registered trade mark

SANOFI 

320524-17

1060029607 - PI DULCOLAX 5MG TABSC M36 GB

Plant: EM CHC
Packaging material code: 1060029607
Packaging material name: PI DULCOLAX 5MG TABSC M36 GB
Second packaging material code: 320524-17
VISTAlink folder number: 4088948
VISTAlink PDF version: 4

This document has been digitally signed by the following people within the VISTAlink system, following the sanofi group guidelines.

Reason	Signed by	Date
Market regulatory validation	Tracey Abbott (UK regulatory team)	26/02/2020 14:57:14
Market health authorities approval	Stephanie Mcgrath (UK regulatory team)	26/02/2020 16:07:03
Plant final technical validation	tristan lorain (EM Delpharm Reims technical packaging team)	12/03/2020 09:02:36
Plant ready to print	Corinne Senon (EM Delpharm Reims Quality packaging team)	12/03/2020 13:46:38