



SOVOLAX 5 mg Tablets

Bisacodyl

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 SOVOLAX 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

1. What SOVOLAX is and what it is used for
2. What you need to know before you take SOVOLAX
3. How to take SOVOLAX
4. Possible side effects
5. How to store SOVOLAX
6. Contents of the pack and other information

1. What SOVOLAX is and what it is used for

SOVOLAX is used for the short-term relief of occasional constipation. SOVOLAX 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 SOVOLAX

Do not take SOVOLAX if you:

- are allergic to bisacodyl 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)
- 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 18 years. If you are not sure, talk to your doctor or pharmacist before taking SOVOLAX.

Warnings and precautions

As with all laxatives, SOVOLAX 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 SOVOLAX

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 SOVOLAX can affect the way some other medicines work. Also, some other medicines can affect the way SOVOLAX 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.
- Other laxative medicines.

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

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.

PAGE 1 of 2	Sovolax
5 mg tablets	
PIP code:	GB 674-7273

Date:	09.01.20	Version 5
Updates:	20.01.20	

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Barcode

SOVOLAX contains lactose 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.

SOVOLAX also contains tartrazine (E102), which may cause allergic reactions.

3. How to take SOVOLAX

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)

1 to 2 tablets.

- 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 SOVOLAX. This is because they will stop SOVOLAX from working properly.

If you have not taken SOVOLAX 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 SOVOLAX 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. It may be harmful to:

- Take too many SOVOLAX tablets
- Take SOVOLAX 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 '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 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 medicine, 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 SOVOLAX

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 SOVOLAX contains

The active substance is bisacodyl.

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

The other ingredients are lactose, maize starch, liquid paraffin, magnesium stearate, polyvinyl acetate phthalate, stearic acid, Opadry® (contains hypromellose, titanium dioxide, polyethylene glycol and tartrazine (E102)) and Carnuba wax.

What SOVOLAX looks like and contents of the pack

SOVOLAX tablets are yellow, shiny, round tablets with no markings.

The tablets are supplied in blisters packed in cartons containing 10 and 20 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

This leaflet was last revised in January 2020

PL 06464/2353 SOVOLAX 5 mg Tablets

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PAGE 2 of 2	Sovolax
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PIP code:	GB 674-7273

Date:	09.01.20	Version 5
Updates:	20.01.20	

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