

# BISALAX<sup>®</sup>

(bisacodyl)

## tablets and enemas

### Consumer Medicine Information (CMI)

---

#### **IMPORTANT**

This leaflet answers some common questions about BISALAX tablets and enemas. It does not replace the advice from your doctor or pharmacist.

**Keep this leaflet with the medicine.** You may need to read it again.

#### **WHAT BISALAX TABLETS OR ENEMAS ARE USED FOR**

BISALAX contains bisacodyl as the active ingredient. Bisacodyl is a stimulant laxative and is used to provide relief from constipation or to empty the large bowel before some medical procedures, operations or X-rays.

It acts on the wall of the large bowel, encouraging bowel movements by increasing muscle contractions which push the stool mass along.

#### **BEFORE TAKING OR USING IT**

***When you must not take or use BISALAX*** BISALAX is not suitable for some patients. You should not take or use this medicine if you have:

- had an allergic reaction to bisacodyl
- stomach cramps, colic or stomach pain
- nausea or vomiting
- blood in the stool
- inflammatory bowel disease
- a condition of the intestine called 'ileus'
- an intestinal obstruction
- severe dehydration
- low potassium levels in the blood

- galactose intolerance.

***Before you start to take or use it***

**Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- had any unusual or allergic reaction to laxatives
- noticed a sudden change in bowel habits or bowel motions, that lasts longer than two weeks
- missed a bowel motion for only a few days.

***Use in the elderly***

Elderly patients may be more sensitive to the effects or side-effects of this medicine.

***Use in children***

**Always ask your doctor or pharmacist before giving any medicines to children.**

BISALAX enemas may be used in children. However, BISALAX tablets are not recommended for use in children under 6 years of age.

***Use in pregnancy or breast feeding***

BISALAX is not known to be harmful in pregnancy or while breast feeding.

However, if you are pregnant or breast feeding you should discuss with your doctor or pharmacist the risks and benefits involved, before taking or using BISALAX.

***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription**

**from your pharmacy, supermarket or health food shop.**

Some medicines and BISALAX may interfere with each other. These include:

- diuretics
- corticosteroids
- digoxin
- some controlled release medicines
- milk products\* (BISALAX tablets only)
- antacids\* (BISALAX tablets only)

\*Milk products and antacids should not be taken within 1 hour, and other medicines within 2 hours, of taking BISALAX tablets.

These medicines may be affected by BISALAX or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking or using BISALAX.

***Interaction with alcohol***

BISALAX has not been shown to increase the effects of alcohol.

***Affect on driving or alertness***

BISALAX does not cause drowsiness and has no known effect on the ability to drive or operate machinery.

**HOW TO TAKE OR USE IT**

BISALAX enemas may be used on their own, or in combination with BISALAX tablets.

**DOSE - Adults**

Depending on the condition being treated, the entire contents of an enema should be inserted into the rectum either in the afternoon, evening or morning according to the dosage guidelines below or as instructed by your doctor.

**DOSE – Adults; for constipation-type conditions:**

Severe constipation:	Initially one enema, then 1 or 2 BISALAX tablets late in the evening and 1 BISALAX enema in the morning (after breakfast) for about 3 days.
Elderly patients:	One BISALAX enema in the morning (after breakfast) on days in which a bowel motion is desired.
Prior to childbirth:	One BISALAX enema immediately before delivery is anticipated.
After childbirth or surgery:	One BISALAX enema to be used immediately after breakfast for two or three days.
After X-ray:	To treat constipation due to barium contrast medium, use one enema.

**DOSE – Adults; to empty the bowel for medical procedures:**

Before X-ray:	The day prior to the examination: take 2 BISALAX tablets at lunchtime and 2 tablets in the evening. The day of the X-ray: One BISALAX enema in the rectum in the morning one to two hours prior to examination.  Note: No food should be eaten from the time of taking BISALAX tablets until after the X-ray has been completed.
Surgery:	As per doctor's instructions.

## DOSE - Children

**BISALAX tablets are not recommended for use in children under 6 years.**

be inserted into the rectum either in the afternoon, evening or morning according to the dosage guidelines below or as instructed by your doctor.

Depending on the child's age, either half or the entire contents of an enema should

### DOSE – Children; for constipation:

Under 3 years:	Half an enema (Note: only half the point of the tube should be inserted).
3 to 6 years:	One enema as required.
6-12 years:	One BISALAX tablet in the evening and one enema in the morning.

### DOSE – Children; to empty the bowel for X-ray examination:

Under 1 year:	Half an enema the night before the examination and half an enema in the morning on the day of the examination.
1 to 3 years:	One enema the night before the examination and one enema in the morning of the day of the examination.
3 to 6 years:	One enema in the afternoon of the day before the examination and one enema in the morning of the day of the examination.
6 to 12 years:	One tablet at 10am and one enema in the afternoon of the day before the examination.
Over 12 years:	Two tablets at 10am and two tablets in the evening of the day before the examination and one enema on the morning of the day of the examination.

## **WHEN AND HOW TO TAKE OR USE THIS MEDICINE**

### **BISALAX tablets**

BISALAX tablets may be taken half an hour before breakfast for an effect in 6-8 hours or at bedtime for a bowel motion in the morning. Tablets are best taken on an empty stomach and should be accompanied by a full glass of fluid, such as water or fruit juice, but not milk.

**Do not chew or crush the tablet as BISALAX tablets are specially coated to allow them to work without causing irritation or nausea. To protect this coating, swallow the tablets whole.**

At least 6-8 glasses of liquid should be taken each day with all kinds of laxatives. This will help to make the stool softer.

### **BISALAX enemas**

BISALAX enemas can be administered at various times throughout the day depending on when an effect is needed. Sometimes, you may need to use it both in the evening and also the following morning.

BISALAX enemas may be used on their own, or in combination with BISALAX tablets. BISALAX enemas may either be self administered, or administered to you by another person.

Instructions for use:

1. Shake the enema well.
2. Take off the yellow cap from the top of the nozzle.
3. If required, lubricate the tip with Vaseline.
4. Lie on your left side with the left leg extended and the right leg bent, in preparation for administration of the enema.

5. Carefully insert the applicator nozzle tip into the rectum, then press on the end of the plastic tube to squeeze the liquid out gently.
6. Remain lying down for a couple of minutes before sitting or standing up.
7. Discard the empty container after use.
8. Visit a toilet as soon as the need to pass a bowel motion occurs.

## **HOW LONG TO TAKE OR USE IT**

**Follow your doctor's or pharmacist's instructions on how long to take or use BISALAX.**

BISALAX should be stopped as soon as normal bowel motions have been re-established. It may not be necessary to finish the whole pack of this medicine.

Under normal circumstances, it is recommended that any laxative should not be used for longer than one week unless directed by a doctor. Prolonged use of laxatives is undesirable, and may lead to dependence and further reliance on the laxative to achieve a bowel motion. This can cause a continuing cycle of constipation.

However, some patients who are no longer able to perform normal bowel motions, may need to use BISALAX enemas on a regular basis for long periods of time.

## **WHAT TO EXPECT**

### **BISALAX tablets**

Individuals vary greatly in their response to BISALAX tablets. After taking BISALAX tablets, a bowel motion should occur approximately 6 - 12 hours later.

### **BISALAX enemas**

After using BISALAX enemas, a bowel motion should normally occur within 5-15 minutes.

## **IF YOU FORGET TO TAKE OR USE IT**

If you miss a dose and if you still need to take or use this medicine, take or use it as soon as you remember.

## **SIDE EFFECTS**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using BISALAX.**

BISALAX helps most people with constipation but they may have unwanted side effects in some people. All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- nausea or vomiting
- stomach cramps, colic or pain
- diarrhoea
- irritation or pain around the anal area.

**Tell your doctor straight away if you notice any of the following symptoms:**

- confusion
- irritability
- headache
- unusual tiredness or weakness
- muscle cramps
- irregular heartbeat
- breathing difficulties.

These symptoms may mean that your body has suffered a large potassium loss. This is a serious side effect. You may need urgent medical attention.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

**Do not be alarmed by this list of side effects.**

You may not experience any of them.

### **IF YOU TAKE OR USE TOO MUCH (OVERDOSE)**

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice if you think that you or anyone else may have taken or used too much BISALAX. Do this even if there are no signs of discomfort or poisoning.**

Signs of overdose include nausea, vomiting, dehydration and stomach pains (for BISALAX tablets) and severe diarrhoea and dehydration (for BISALAX enemas).

### **AFTER TAKING OR USING IT**

#### ***Storage***

Keep BISALAX in a safe place, out of the reach of children. Do not use this medicine after the expiry date printed on the packaging.

#### **BISALAX tablets**

Store BISALAX tablets in the original packaging, at a temperature below 25°C and away from direct light and moisture.

#### **BISALAX enemas**

Store BISALAX enemas in the original packaging at a temperature of 2°C to 8°C (Refrigerate. Do not freeze). Before use, allow the enema to reach room temperature.

#### ***Disposal***

Ask your pharmacist what to do with any BISALAX you may have left over, if you no longer require them, or if you find it has passed the expiry date.

### **PRODUCT DESCRIPTION**

#### ***What it looks like*** **BISALAX tablets**

Yellow, round, convex enteric coated tablets with no scoring. Available in bottles of 200 tablets.

#### **BISALAX enemas**

Yellow tube with yellow flip off cap which contains a white to grey viscous material. Available in packs of 25 enemas.

#### ***Ingredients***

#### **BISALAX tablets**

Active ingredient: Each tablet contains 5 mg bisacodyl.

Inactive ingredients include lactose, starch maize, macrogol 6000, glycerol, gelatin, magnesium stearate, silica colloidal anhydrous, hypromellose, propylene glycol, hypromellose phthalate, diethyl phthalate and quinoline yellow CI 47005.

#### **BISALAX enemas**

Active ingredient: Each enema contains 10 mg bisacodyl.

Inactive ingredients include citric acid monohydrate, macrogol 3000, macrogol 400, macrogol 4000 and sodium citrate.

### **SPONSOR**

Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos St  
St Leonards NSW 2065  
AUSTRALIA

Australian registration numbers:  
AUST R 72491 (BISALAX tablets)  
AUST R 27900 (BISALAX enemas)

BISALAX is the registered trade mark of Ercopharm A/S, Denmark

This leaflet was revised in September 2013.