

PELAX

(Bisacodyl) BP
5 mg Gastro-resistant Tablets

COMPOSITION:

Each enteric coated tablet contains:

Bisacodyl BP.....5mg

GENERAL INFORMATION:

This medicine is available without prescription. You need to take PELAX 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.

INDICATION:

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

CONTRAINDICATIONS:

- You are allergic (hypersensitive) to bisacodyl or any of the other ingredients in the product.
 - You are intolerant to or cannot digest some sugars (as the tablet contains a small amount of lactose).
 - 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.

Pregnancy and breast feeding:

Talk to your pharmacist or doctor before taking PELAX 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.

DRUG INTERACTION:

Please tell your 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 PELAX 5mg Tablets can affect the way some other medicines work, also some other medicines can affect the way PELAX 5mg Tablets work.

IN PARTICULAR:

- Water tablets (diuretics) such as bendrofluzide or furosemide (frusemide) and steroid medicines such as prednisolone may increase risk of electrolyte imbalance.
- Other laxative medicines.
- Cimetidine, as decreased effectiveness of PELAX Tablet.
- Milk, gastric or duodenal irritation.
- Calcium, decreased effectiveness of PELAX.

DOSAGE AND ADMINISTRATION:

As with all laxatives, PELAX 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 PELAX Tablets. This is because they will stop the PELAX Tablets from working properly.

Adults and children over 10 years:

- Take one or two tablets (5 or 10 mg) daily before bedtime.
- If you have not taken PELAX 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:

PELAX 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

PELAX Tablets are not recommended for children under 4 years.

OVER DOSAGE:

It may be harmful to

- Take too many PELAX Tablets or
- Take PELAX 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.

SIDE EFFECTS:

Like all medicines, PELAX 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.
- Faintings.

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.

STORAGE

- Keep this medicine out of the sight & reach of children.
- Store below 30°C, or protect from heat, light and moisture.

HOW SUPPLIED:

PELAX Tablets are orange yellow. They are available in packs of 10X10's Per Box.



Manufactured By:
SIGMA PHARMA (International Private Limited.)
E50 North Western Industrial Zone
Port Qasim Authority, Karachi-Pakistan
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