1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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LAXADOR BISACODYL SUPPOSITORIES 10 mg

Bisacodyl

Read all of this leaflet carefully because it contains important information for you

LAXADOR BISACODYL SUPPOSITORIES are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use LAXADOR BISACODYL SUPPOSITORIES carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LAXADOR BISACODYL SUPPOSITORIES with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

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

1. What LAXADOR BISACODYL SUPPOSITORIES is and what it is used for

LAXADOR BISACODYL SUPPOSITORIES contain bisacodyl and belongs to a group of medicines called laxatives, which increase bowel movements.

LAXADOR BISACODYL SUPPOSITORIES are used for the treatment of occasional constipation.

LAXADOR BISACODYL SUPPOSITORIES does not help with weight loss.

2. What you need to know before you use LAXADOR BISACODYL SUPPOSITORIES

Do not use LAXADOR BISACODYL SUPPOSITORIES:

- If you are hypersensitive (allergic) to bisacodyl or any of the other ingredients of LAXADOR BISACODYL SUPPOSITORIES (listed in section 6),
- if you have a bowel condition called ileus (causing a blockage in your intestine),
- if you suffer from a blocked bowel (intestinal obstruction/ileus),
- if you have a serious undiagnosed abdominal condition, such as acute appendicitis,
- if you suffer from inflammation of the bowel (small or large intestine),
- if you have severe abdominal pain with nausea and vomiting which may be signs of a more serious abdominal condition,
- if you are dehydrated,
- if you have cracking of the skin around your back passage (anal fissures),
- if you have inflammation or ulcers around your back passage (ulcerative proctitis).

Warnings and precautions

Take special care with LAXADOR BISACODYL SUPPOSITORIES:

- if your symptoms worsen whilst using LAXADOR BISACODYL SUPPOSITORIES, if you notice blood in your stool or if you do not have a stool after using LAXADOR BISACODYL SUPPOSITORIES you should contact your healthcare provider. This can be an indication of a more serious underlying condition,
- if you suffer from chronic constipation. LAXADOR BISACODYL SUPPOSITORIES should not be used for longer than 7 days (see 3. How to use LAXADOR BISACODYL SUPPOSITORIES). If it is needed every day, the cause of constipation should be investigated,
- repeated use may lead to inflammation of the lining of the rectum (proctitis),
- if you have noticed a sudden change in your bowel habits that has persisted for a period of greater than 2 weeks, consult a doctor before using LAXADOR BISACODYL SUPPOSITORIES,
- if you have kidney problems,
- if you are elderly,
- if you suffer from rectal fissures or ulcerated haemorrhoids the use of LAXADOR BISACODYL SUPPOSITORIES may cause painful sensations and local irritation.

It is recommended to make changes to your diet and use bulk forming medicines to control constipation before using LAXADOR BISACODYL SUPPOSITORIES. 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.

Frequent or prolonged use of LAXADOR BISACODYL SUPPOSITORIES may result in dependence on laxatives, loss of electrolytes and loss of normal bowel function.

If you experience any rectal bleeding, bloody stools or you do not have a bowel movement after using LAXADOR BISACODYL SUPPOSITORIES, stop using LAXADOR BISACODYL SUPPOSITORIES and contact your doctor.

LAXADOR BISACODYL SUPPOSITORIES does not help with weight loss. It does not reduce the absorption of calories or nutrients. It can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

Overuse of laxatives, such as LAXADOR BISACODYL SUPPOSITORIES, 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 your heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs in your body;

• 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 of your body.

Other medicines and LAXADOR BISACODYL SUPPOSITORIES

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Diuretic medicines (used to treat high blood pressure or help eliminate excess water and salt from the body) and steroid medicines such as prednisolone (used to treat inflammation in different areas of your body) as this may increase the risk of electrolyte imbalance if excessive doses of LAXADOR BISACODYL SUPPOSITORIES are used.
- Cardio glycosides (used to treat heart failure or irregular heartbeats), as electrolyte imbalance may cause increased sensitivity to the effects of cardiac glycosides.
- Other laxatives (used to treat constipation) as this may worsen the undesirable effects that LAXADOR BISACODYL SUPPOSITORIES can have on your digestive tract.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

Safety and efficacy of LAXADOR BISACODYL SUPPOSITORIES during pregnancy and lactation have not been established.

Driving and using machines

LAXADOR BISACODYL SUPPOSITORIES can cause side effects such as dizziness or fainting. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how LAXADOR BISACODYL SUPPOSITORIES affects you.

It is not always possible to predict to what extent LAXADOR BISACODYL SUPPOSITORIES may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LAXADOR BISACODYL SUPPOSITORIES affects you (see section 4).

LAXADOR BISACODYL SUPPOSITORIES contains

Lactose, Suppocire AM

3. How to use LAXADOR BISACODYL SUPPOSITORIES

Do not share medicines prescribed for you with any other person.

Always use LAXADOR BISACODYL SUPPOSITORIES exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose of LAXADOR BISACODYL SUPPOSITORIES is:

Adults and children 12 years and over:

The usual dose is one 10 mg suppository as a single daily dose.

Do not use for longer than 7 days.

The suppositories should only be used in your back passage.

1. Take off the foil wrapping.

2. Lie on one side and pull your knees up towards your chest. Keep one leg drawn up more than the other.

3. Use your first finger (index finger) or middle finger to push in the suppository, pointed end first.

4. Gently push the suppository as far as possible into your back passage, pointed end first.

5. Once it is as far as it will go, push it side-ways to make sure it touches the wall of the bowel.

6. Lower your legs to a comfortable position whilst the suppository is retained in place.

If you feel the suppository might come out straight away:

You may not have put it in high enough. Push it in as far as possible.

Do not exceed the recommended dosage.

If you use more LAXADOR BISACODYL SUPPOSITORIES than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If high doses are used you may experience watery stools (diarrhoea) and abdominal cramps.

Take this leaflet and the rest of the remaining LAXADOR BISACODYL SUPPOSITORIES with you so the doctor will know what you have used.

If you forget to use LAXADOR BISACODYL SUPPOSITORIES

Do not use a double dose to make up for forgotten individual doses.

If you stop using LAXADOR BISACODYL SUPPOSITORIES

LAXADOR BISACODYL SUPPOSITORIES should only be used when you are constipated. It should not be used for more than 7 days. Do not use a double dose.

4. Possible side effects

LAXADOR BISACODYL SUPPOSITORIES can have side effects.

Not all side effects reported for LAXADOR BISACODYL SUPPOSITORIES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using LAXADOR BISACODYL SUPPOSITORIES, please consult your healthcare provider for advice.

If any of the following happens, stop using LAXADOR BISACODYL SUPPOSITORIES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LAXADOR BISACODYL SUPPOSITORIES. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Abdominal pain, cramping or tenderness, blood in stool, feeling of urgency of bowel movements, diarrhoea and nausea as these may be symptoms of inflammation of or reduced blood flow to the large intestine (colitis; ischaemic colitis).
- Increased thirst, dry mouth, shaking, swollen tongue, weakness, confusion, blurry vision, passing less urine than normal and fainting as these may be symptoms that you have lost more fluid than you have taken in, and your body doesn't have enough water and other fluids to carry out its normal functions (dehydration).

- Nausea and/or vomiting, sweaty palms, light headedness, blacking out or seeing spots or having tunnel vision as these may be symptoms of syncope (fainting or passing out).
- Blood in the stool (haematochezia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea,
- diarrhoea,
- cramps or pain in your stomach area.

Less frequent side effects:

- Dizziness,
- vomiting (being sick),
- discomfort in the stomach or back passage area.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA** via the Med Safety APP (Medsafety X SAHPRA) and eReporting

platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LAXADOR BISACODYL SUPPOSITORIES.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of LAXADOR BISACODYL SUPPOSITORIES.

5. How to store LAXADOR BISACODYL SUPPOSITORIES

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Store in well-closed containers.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LAXADOR BISACODYL SUPPOSITORIES contains

The active substance is 10 mg of bisacodyl.

The other ingredients are Lactose, Suppocire AM.

What LAXADOR BISACODYL SUPPOSITORIES looks like and contents of the pack

LAXADOR BISACODYL SUPPOSITORIES is a white torpedo-shaped suppository.

Opaque white, PVC laminated to polyethylene, film casings, in packs of individually sealed 5, 10, 50 or 250 suppositories (in strips of 5). Each opaque white suppository case has the name of the product and the applicant printed in red, on one side and is plain on the other side.

The strips are packed together with a package insert into a cardboard carton.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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