NEW ZEALAND CONSUMER MEDICINE INFORMATION

BISACODYL VIATRIS

Bisacodyl enteric coated tablet 5 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Bisacodyl Viatris.

This leaflet answers some common questions about Bisacodyl Viatris.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Bisacodyl Viatris against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

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

What Bisacodyl Viatris is used for

Bisacodyl Viatris is used to treat constipation.

Under medical supervision, Bisacodyl Viatris can be used for the evacuation of the bowel before a radiological examination or as an enema alternative.

Bisacodyl Viatris contains the active ingredient bisacodyl. It belongs to a group of medicines called stimulant laxatives.

It works by acting on the lining of the lower bowel to stimulate movement and promotes accumulation of water into the bowel to product soft formed stools.

Bisacodyl Viatris is ineffective in altering the digestion or absorption

of calories or essential nutrients in the small intestine.

Stimulant laxatives including Bisacodyl Viatris do not help with weight loss.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine can be purchased from a pharmacist without a doctor's prescription.

Before you take Bisacodyl Viatris

When you must not [take it

Do not take Bisacodyl Viatris if you have an allergy to:

- any medicine containing bisacodyl
- any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use Bisacodyl Viatris if you have, or have had, any of the following conditions:

- An acute abdominal condition including appendicitis
- Acute inflammatory bowel disease
- Severe abdominal pain associated with nausea and vomiting



- Blockage of the bowel (ileus)
- A blockage of the intestine
- Severe dehydration

Do not give this medicine to a child under the age of 4 years. Safety and effectiveness in children younger than 4 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

Special care is recommended during pregnancy. The benefits of Bisacodyl Viatris must be assessed against any risks. Your doctor will discuss the risks and benefits of using Bisacodyl Viatris while you are pregnant.

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed. This medicine can be used during breastfeeding if the expected benefit is deemed to outweigh the potential risk by your doctor.

If you have not told your doctor about any of the above, tell them before you start taking Bisacodyl Viatris.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, you should tell your doctor or pharmacist if you are taking:

- Diuretics (medicines that increase urine volume)
- Corticosteroids
- Medicines which stimulate the heart e.g. digoxin.
- Medicines that reduce the acidity of the upper gastrointestinal tract

You should also tell any health professional who is prescribing a new medication for you that you are taking Bisacodyl Viatris. It is important to discuss this with your doctor or pharmacist because Bisacodyl Viatris may not work as well in the presence of some other medicines or side effects may be increased.

Bisacodyl Viatris should not be taken together with milk and products that reduce the acidity of the upper gastrointestinal tract.

Use of Bisacodyl Viatris with other laxative may enhance gastrointestinal side effects.

After taking Bisacodyl Viatris, avoid straining while passing a bowel motion.

Dizziness and fainting while straining have been reported in patients taking bisacodyl, however the cause is unknown.

You may experience blood in the stool while using Bisacodyl Viatris. This is generally mild and selflimiting. Tell your doctor if you notice this and it worries you.

Bisacodyl Viatris is recommended for short term use only. If symptoms persist, seek medical advice.

Long term use of Bisacodyl Viatris is not recommended. If you use

Bisacodyl Viatris every day, you should consult with your doctor to find out the cause of your constipation.

Long term and excessive use of Bisacodyl Viatris may cause an imbalance of salts in the body (including low potassium), muscle weakness and kidney problems. Loss of fluids from the body can cause dehydration. Symptoms of dehydration include thirst and passing less urine than normal. In patients experiencing fluid loss where dehydration may be harmful (for example, kidney problem, elderly patients), Bisacodyl Viatris should be stopped and only restarted under medical supervision.

Long term and excessive use may also cause the bowel to become dependent on Bisacodyl Viatris for it to produce a bowel motion.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Bisacodyl Viatris

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Bisacodyl Viatris should be taken as needed to relieve constipation. It is recommended to start with the lowest dose. The dose may be adjusted up to the maximum recommended dose to produce regular stools. The maximum daily dose should not be exceeded.

For adults and children over 10 years old, use one or two Bisacodyl Viatris tablets at night. For children aged 4 to 10 years, one Bisacodyl Viatris tablet at night. Bisacodyl Viatris is not recommended in children under 4 years of age.

How to take it

Swallow the tablets whole with a full glass of water. Do not crush or chew the tablet.

Do not take Bisacodyl Viatris tablets together with medicines that lower acidity of the upper gastrointestinal tract (stomach). These medicines may include antacids, and a group of medicines called proton pump inhibitors. If you think you may be taking any of these medicines, please speak with your doctor or pharmacist.

Do not have milk or antacids within 1 hour of taking Bisacodyl Viatris tablets. These may affect how well Bisacodyl Viatris tablets work.

Bisacodyl Viatris tablets usually work in 6 - 12 hours.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Bisacodyl Viatris

Things you must do

If you are about to be started on any new medicine, tell your

doctor and pharmacist that you are taking Bisacodyl Viatris.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Drink plenty of water while taking laxatives.

An increase in fibre in your diet is recommended, except in the cases of medication-induced constipation.

You should discuss with your doctor or pharmacist if you need to increase the fibre in your diet when using Bisacodyl Viatris to assist in the treatment of constipation.

Things you must not do

Do not take Bisacodyl Viatris to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Bisacodyl Viatris affects you. This medicine may cause dizziness or syncope in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have [used/taken] too much [Trade name]. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- Diarrhoea
- Abdominal cramps
- Fluid loss
- Imbalance of salt in the body (including low potassium).

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Bisacodyl Viatris.

This medicine helps most people with constipation, but it may have unwanted side effects in a few people.

All medicines can 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:

- Colitis including ischaemic colitis
- Abdominal discomfort
- Abdominal cramps
- Nausea
- Vomiting
- Diarrhoea
- Anorectal discomfort
- Blood in the stools
- Dehydration
- Dizziness
- Fainting

Abdominal pain and diarrhoea are the most commonly reported side effects. These side effects are usually mild and short lived.

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Rash, itching or hives on the skin
- Swelling of the face, lips, tongue or other parts of the body
- Shortness of breath, wheezing or trouble breathing.

These are the symptoms of lifethreatening allergic (anaphylactic) reactions. These are serious side effects. You may need urgent medical attention or hospitalization. Serious side effects are rare.

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

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Bisacodyl Viatris

Storage

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Bisacodyl Viatris or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Yellow round biconvex coated tablets.

Ingredients

<u>Active ingredient:</u> Bisacodyl Viatris contains 5 mg of bisacodyl as the active ingredient.

<u>Inactive ingredients:</u> Bisacodyl Viatris also contains:

Core:

- Lactose monohydrate
- Microcrystalline cellulose
- Hydroxyl propyl cellulose

- Pregelatinised starch
- Magnesium stearate

Coating:

- Hypromellose
- Triethyl citrate
- Purified talc
- Eudragit L 100
- Eudragit S 100
- Isopropyl alcohol
- Sucrose
- Hypromellose
- Magnesium stearate
- Titanium dioxide
- iron oxide yellow
- Carnauba wax

Contains lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Bisacodyl Viatris is supplied in New Zealand by:

Viatris Ltd PO Box 11-183 Ellerslie AUCKLAND <u>www.viatris.co.nz</u> Telephone 0800 168 169

Date of Preparation

08 August 2024 (Based on datasheet 08 August 2024)