

PATIENT INFORMATION LEAFLET FOR BISOCET

SCHEDULING STATUS **S0**

BISOCET 5 mg suppositories

BISOCET 10 mg suppositories

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

BISOCET is available without a doctor's prescription, for you or your child to treat a mild illness. Nevertheless, you still need to use BISOCET carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BISOCET with any other person.
- Ask your health care 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 BISOCET is and what it is used for
2. What you need to know before you use BISOECT
3. How to use BISOCET
4. Possible side effects
5. How to store BISOCET
6. Contents of the pack and other information

1. What BISOET is and what it is used for

BISOCET suppositories contain bisacodyl and belong to a group of medicines known as stimulant laxatives, which increase bowel movements. BISOCET suppositories are used for short-term



relief of occasional constipation.

BISOET suppositories does not help with weight loss.

2. What you need to know before you use BISOET

Do not use BISOET:

- If you or your child are hypersensitive (allergic) to bisacodyl or any of the other ingredients of BISOET (listed in section 6).
- If you or your child have a bowel condition call ileus (causing a blockage in your intestine).
- If you or child suffer from a blocked bowel (intestinal obstruction).
- If you or your child have a serious abdominal condition, such as appendicitis.
- If you or your child suffer from inflammation of the bowel (small or large intestine)
- If you or your child have severe abdominal pain with nausea and vomiting.
- If you or your child are severely dehydrated.
- If you or your child have cracking of the skin around your back passage (anal fissures).
- If you or your child have inflammation or ulcers around your back passage (ulcerative proctitis).

Warnings and precautions

Take special care with BISOET:

- If you or your child suffer from chronic constipation. BISOET should not be used for longer than 7 days.
- If you or your child 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 BISOET.
- If you or your child have kidney problems.
- If you are elderly.

It is recommended to make changes in your or your child's diet and use bulk forming medicines to

control constipation before using BISOCET.

If you or your child experience any rectal bleeding, bloody stools or you do not have a bowel movement after using BISOCET, stop the use of BISOCET and contact your doctor.

BISOCET 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 BISOCET, may damage your or your child's health by:

- Causing disturbance 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 the 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.

Children and adolescents

BISOCET should not be given to children without medical advice.

Other medicines and BISOCET

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you or your child are currently using:

- Diuretic medicines (used to treat high blood pressure or help to eliminate excess water and salt from the body).

- Steroid medicines (used to treat inflammation).
- Cardio glycosides (used to treat heart failure or irregular heart beats).
- Other laxatives (used to treat constipation).

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 health care provider for advice before using this medicine.

Safety and efficacy of BISOCET during pregnancy and lactation have not been established.

Driving and using machines

BISOCET 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 BISOCET affects you.

3. How to use BISOCET

Always use BISOCET exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Bowel movement is generally produced within 15 minutes to one hour. The recommended dose is:

Adults and children 12 years and over:

One 10 mg suppository as a single daily dose.

Children 1-12 years: one 5 mg suppository as a single daily dose.

One 5 mg suppository as a single daily dose

The suppository 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.
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.

If you have the impression that the effect of BISOCET is too strong or too weak, tell your doctor or pharmacist.

If you use more BISOCET than you should

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

If you forget to use BISOCET

BISOCET should only be used when you or your child are constipated. It should not be used for more than 7 days. Do not take a double dose.

4. Possible side effects

BISOCET can have side effects.

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

If any of the following happens to you or your child, stop using BISOCET and tell your doctor or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting.

These are all very serious side effects. If you or your child has them, you may have had a serious reaction to BISOCET. You or your child 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:

Side effects occurring less frequently:

- Dehydration (may cause tremors, weakness, blurry vision, fainting, feeling faint, increased thirst, headaches, passing less urine than normal).

This is a serious side effects. You or our child may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Stomach cramps, stomach pain
- Diarrhoea,
- Nausea (feeling sick).

Less frequent side effects:

- Allergic reactions,
- Swelling around the face or lips (angioedema),

- Dizziness, fainting,
- Blood in the stool,
- Vomiting (being sick),
- Rectal (back passage) pain,
- Inflamed colon.

If you or your child 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 or pharmacist. You can also report side effects to found of SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) on SAHPRA website. By reporting side effects, you can help provide more information on the safety BISOCET.

5. How to store BISOCET

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the blister strip in the outer carton in order to protect from light.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What BISOCET contains:

BISOCET 5 contains 5 mg bisacodyl.

BISOECT 10 contains 10 mg bisacodyl.

The other ingredient is hard fat.

What BISOCET looks like and contents of the pack

BISOCET 5: white opaque, bullet shaped suppositories.

BISOCET 10: white opaque, bullet shaped suppositories.

BISOCET are packed in a PVC/PVDC/PE and ALU/PE film preformed blister.

BISOCET contains 2 strips of 5 suppositories, packed in an outer carton.

Pack size: 10 suppositories.

Holder of certificate of registration

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Registration number

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