

Buscopan coated tablets, 10 mg

butylscopolamine bromide

Read the entire leaflet carefully before using this medicine, as it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

What Buscopan coated tablets are and what they are used for

- Buscopan coated tablets are tablets containing butylscopolamine bromide as the active ingredient.
- Buscopan coated tablets are a medication that relieves spasms (spasmolytic).
- Buscopan coated tablets are used to treat spasms (cramps) of the gastrointestinal tract.

When you should not use this medicine or take extra care

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- You have a certain abnormality in the colon (megacolon).
- You have a bowel obstruction.
- You have narrowings in the gastrointestinal tract.
- You have a certain muscle disease (myasthenia gravis).
- If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.
- When should you take extra care with this medicine?
- During episodes of cramping pain caused by gallstones or kidney stones.
- Buscopan coated tablets are not effective in these episodes. Spasms (or pain resulting from them) can be a symptom of a serious underlying condition.
- You are predisposed to increased eye pressure (narrow-angle glaucoma).
- You have an increased risk of blockages (obstructions) of the intestines and/or urinary tract.
- You have heart rhythm disorders.

If severe unexplained abdominal pain persists, worsens, or occurs simultaneously with symptoms such as fever, nausea, vomiting, changes in bowel movements, sensitivity in the lower abdomen, low blood pressure, fainting, or blood in the stool, you should immediately contact your doctor.

Contact your doctor before using this medication if any of the above warnings apply to you, or if they have in the past.

Are you taking any other medications?

If you are taking other medications in addition to Buscopan coated tablets, have taken them recently, or may use other medications in the near future, tell your doctor or pharmacist. This also applies to medications that do not require a prescription.

When you use Buscopan coated tablets together with one of the following medications, the effect of one or both medications may be affected:

- certain medications for depression (tri- and tetracyclic antidepressants)
- certain medications for allergies (antihistamines)
- certain medications for psychosis (antipsychotics)
- certain class of medications for heart rhythm disorders (quinidine and disopyramide)
- certain medication for Parkinson's disease or virus infections (amantadine)
- other medications with the same effect as Buscopan (e.g. tiotropium, ipratropium, atropine-like agents)
- medications that counteract the effect of dopamine (such as metoclopramide and domperidone) - the effect of both medications may be reduced as a result
- medications that increase heart rate - the effect of these medications may be enhanced
- substances with the same effect as Buscopan coated tablets - the effects may be influenced.

Pregnancy and breastfeeding: Are you pregnant, think you may be pregnant, planning to become pregnant, or breastfeeding? Then contact your doctor or pharmacist before using this medicine.

There is insufficient data on the use of Buscopan coated tablets during pregnancy to assess their possible harmful effects. Therefore, the use of Buscopan coated tablets during pregnancy is not recommended.

There is also insufficient data available on the use of Buscopan coated tablets during breastfeeding to assess their possible harmful effects. Therefore, the use of Buscopan coated tablets is not recommended during breastfeeding.

Driving and using machines: There is no research on the effect of Buscopan coated tablets on driving ability and the ability to operate machinery.

How to use this medication?

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. If you are unsure about the correct use, please contact your doctor or pharmacist.

Adults: The recommended dosage for adults is one to two coated tablets three to five times a day.

Children aged 6 years and older: The recommended dosage for children aged 6 years and older is one to two coated tablets three to five times a day.

Buscopan should not be used day after day or for a longer period without your doctor investigating the cause of your abdominal pain.

You should swallow the coated tablets whole with some water or milk (do not chew them).

Have you taken too much of this medication?

If you have taken too many Buscopan coated tablets, you may experience an increased heart rate, dry mouth, blurred vision, retention of urine, skin redness, and reduced stomach and bowel function.

These side effects are usually mild and short-lived. If you experience these symptoms, stop taking

Buscopan coated tablets and contact your doctor.

Have you forgotten to take this medication?

Do not take a double dose to make up for a forgotten dose.

If you stop taking this medication.: If you suddenly stop using Buscopan coated tablets, the symptoms you had before use may return.

Possible side effects: Like any medicine, this medicine can have side effects, although not everyone experiences them. Many of the side effects listed below can be attributed to the action of Buscopan. These side effects are generally mild and short-lived. Some side effects can be serious. The exact frequency of these side effects cannot be determined, but it is certainly no higher than sometimes (in less than 1 out of 100 users). If you experience any of the following side effects, contact your doctor immediately:

severe allergic reaction to certain substances, resulting in a sudden and severe dilation of blood vessels, leading to a significant drop in blood pressure, paleness, restlessness, weak and rapid pulse, clammy skin, and decreased consciousness (anaphylactic shock)

severe life-threatening allergic reaction to certain substances (anaphylactic reaction).

Other side effects: Some side effects may sometimes occur (in less than 1 out of 100 users): skin reactions, accelerated heart rate (tachycardia), dry mouth, disturbance of sweating, skin rash with severe itching (urticaria) and formation of bumps (hives), itching.

Some side effects may rarely occur (in less than 1 out of 1000 users): retention of urine in the bladder due to impaired bladder emptying (urinary retention), The exact frequency of the following side effects cannot be determined, but it is certainly no higher than sometimes (in less than 1 out of 100 users): shortness of breath (dyspnea), hypersensitivity, skin rash, redness of the skin (erythema).

How to store this medicine?

- Keep out of sight and reach of children.
- Store below 25°C.
- Do not use this medicine after the expiry date. The expiry date is printed on the package after "EXP". It shows a month and a year. The last day of that month is the expiry date.