

Package leaflet: information for the user
Buscopan coated tablets, 10 mg
Butylscopolamine bromide

Read the entire leaflet carefully before you start using this medicine, because 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.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Then contact your pharmacist.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.
- Does your complaint not improve after 14 days, or does it even get worse? Then contact your doctor.

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1. What are Buscopan coated tablets and what are they used for?

Buscopan coated tablets are tablets with butylscopolamine bromide as the active substance. Buscopan coated tablets is a medication that relieves spasms (spasmolytic). Buscopan coated tablets are used for the treatment of spasms (cramps) of the gastrointestinal tract.

2. When should you not use this medicine or be extra careful with it?

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 suffer from a certain abnormality of the large intestine (megacolon).
- You suffer from an intestinal obstruction.
- You have strictures in the gastrointestinal tract.
- You have a certain muscle disease (myasthenia gravis).
- If your doctor has told you that you do not tolerate certain sugars, contact your doctor before taking this medicine.

When should you be extra careful with this medicine?

- In cases of cramping pains resulting from gallstones or kidney stones. In these cases, Buscopan coated tablets are not effective. Spasms (or pain resulting from them) can be a symptom of a serious underlying condition.
- You have a predisposition to increased eye pressure (narrow-angle glaucoma).
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- You have an increased risk of 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, tenderness in the lower abdomen, low blood pressure, fainting, or blood in the stool, you should contact your doctor immediately.

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

Are you using any other medicines?

Are you using any other medicines besides Buscopan coated tablets, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

When you use Buscopan coated tablets together with any of the following medicines, the effect of either medicine may be influenced:

- certain medicines for depression (tri- and tetracyclic antidepressants)
- certain medicines for allergies (antihistamines)
- certain medicines for psychoses (antipsychotics)
- certain class of medicines for heart rhythm disorders (quinidine and disopyramide)
- certain medicine for Parkinson's disease or viral infections (amantadine)
- other medicines with the same effect as Buscopan (e.g., tiotropium, ipratropium, atropine-like agents)
- medicines that counteract the effect of dopamine (e.g., metoclopramide and domperidone) – this may reduce the effect of both medicines
- medicines that increase heart rate – their effect may be enhanced
- substances with the same effect as Buscopan coated tablets – their effects may be influenced.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you 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 potential harm. Therefore, the use of Buscopan coated tablets during pregnancy is not recommended.

There is also insufficient data available on the use during breastfeeding to assess potential harm. Therefore, the use of Buscopan coated tablets during breastfeeding is also not recommended.

Driving and using machines

No studies have been conducted on the effect on driving ability and the ability to operate machines.

3. How to use this medicine?

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Adults

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

Children from 6 years

The recommended dosage for children from 6 years is one to two coated tablets three to five times a day.

Buscopan should not be used day in and day out or for a prolonged period without your doctor investigating the cause of your abdominal pain.

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

Have you taken too much of this medicine?

If you have taken too many Buscopan coated tablets, you may experience an increased heart rate, dry mouth, blurred vision, urinary retention, skin redness, and reduced stomach and bowel function. These side effects are usually mild and short-lived. Are you experiencing these symptoms? Then stop taking Buscopan coated tablets and contact your doctor.

Have you forgotten to take this medicine?

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

If you stop taking this medicine.

When you suddenly stop using Buscopan coated tablets, the symptoms you had before using may return.

4. Possible side effects

Like all medicines, this medicine can have side effects, although not everyone gets 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. How often these side effects occur cannot be precisely determined, but it is certainly not higher than occasionally (in less than 1 in 100 users). Are you experiencing any of the side effects listed below? Then contact your doctor immediately.

- severe allergic reaction to certain substances, with a strong drop in blood pressure, paleness, restlessness, weak rapid pulse, clammy skin, and reduced consciousness occurring as a result of a sudden, strong vasodilation (anaphylactic shock)
- severe, life-threatening allergic reaction to certain substances (anaphylactic reaction).

Other side effects

Some side effects can sometimes occur (in less than 1 in 100 users):

- skin reactions
- increased heart rate (tachycardia)
- dry mouth
- disturbance of sweating
- skin rash with severe itching (hives) and formation of welts (urticaria)
- itching.

Some side effects may rarely occur (in less than 1 in 1000 users):

- retention of urine in the bladder due to impaired bladder emptying (urinary retention).

The frequency of the following side effects cannot be determined exactly, but it is certainly not higher than occasionally (in less than 1 in 100 users):

- shortness of breath (dyspnea)
- hypersensitivity
- skin rash
- redness of the skin (erythema).

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb (www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date. This can be found on the packaging after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is butylscopolamine bromide. One coated tablet contains 10 mg butylscopolamine bromide.
- The other ingredients in this medicine are: calcium hydrogen phosphate (E341), corn starch, starch (soluble), colloidal silica (E551), tartaric acid (E334), stearic acid (E570), povidone (E1201), sucrose, talc (E553b), gum arabic (E414), titanium dioxide (E171), polyethylene glycol 6000, carnauba wax and white wax.

What do Buscopan coated tablets look like and how many are in a package?

Buscopan coated tablets are white, round coated tablets.

Buscopan coated tablets are supplied in blister packs of 20, 30, 50, or 100 coated tablets. It may happen that not all pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Opella Healthcare France SAS

157 avenue Charles de Gaulle

92200 Neuilly-sur-Seine

France

For correspondence and inquiries

Healthypharm B.V.
Van de Reijtstraat 31-E
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