



10mg, coated tablet
hyoscine butylbromide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take 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.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

- What is in this leaflet:**
1. What Buscopan is and what it is used for
 2. What you need to know before you take Buscopan
 3. How to take Buscopan
 4. Possible side effects
 5. How to store Buscopan
 6. Further information

1. WHAT BUSCOPAN IS AND WHAT IT IS USED FOR

Buscopan is a cramp-relieving (antispasmodic) agent. Buscopan is used to treat mild to moderate cramps of the gastrointestinal tract and to treat cramp-like abdominal pain in irritable bowel syndrome.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BUSCOPAN

Contraindications:

Do not take BUSCOPAN

- If you are allergic to hyoscine butylbromide or any of the other ingredients of this medicine (listed in section 6)
- If you have or suspect to have a mechanical narrowing (stenosis) of the gastrointestinal tract (e.g. because of an ulcer or kinking of the bowel)
- If your bowel is blocked and doesn't work correctly (paralytical or obstructive ileus). Symptoms include severe abdominal pain with lack of bowel movement and/or nausea/vomiting.
- If you have abnormal widening of the large bowel (megacolon)
- If you have urinary retention due to mechanical narrowing of the urinary tract (e.g. enlargement of the prostate gland)
- If you have narrow-angle glaucoma
- If you have an abnormally fast heart rate, palpitations and an irregular heartbeat
- If you have myasthenia gravis
(a particular form of abnormal muscle weakness)

Appropriate precautions for use; special warnings:

Warnings and precautions

Talk to your doctor or pharmacist before taking Buscopan. Consult a doctor immediately if severe abdominal pain persists, worsens or occurs in conjunction with other symptoms (such as fever, nausea, vomiting, changes of bowel motility, tenderness in the abdomen, fall in blood pressure, unconsciousness or blood in the stool).
One coated-tablet contains about 41 mg of sucrose (sugar). Patients with certain rare metabolic diseases (fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase deficiency) should not take Buscopan.

Children:

Do not give Buscopan to children under 6 years of age as there is insufficient experience in this age group to date.

Other medicines and Buscopan:

Tell your doctor or pharmacist if you are taking or using, have recently taken or used or might take or use any other medicines.
The anticholinergic effects described in the side effects section can occur to an increased extent if Buscopan is used simultaneously with other medicines that themselves can cause such effects, e.g. other anticholinergics (tiotropium, ipratropium, atropine-like compounds), amantadine, tricyclic and tetracyclic antidepressants, antipsychotics, quinidine, disopyramide and antihistamines.
Concomitant therapy with dopamine antagonists, such as metoclopramide, can result in a mutual weakening of the effect on the muscles of the gastrointestinal tract. Buscopan can also intensify the heart-rate accelerating effect of β -sympathomimetics.
The medicines mentioned are used for various conditions, such as viral diseases, depression, heart rhythm disorders, allergies, stomach emptying disorders, asthma and colds, as well as for weight loss.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy:

There is insufficient experience to date with the use of Buscopan in pregnant women. There are no adequate animal studies that indicate possible unwanted or harmful effects of use in pregnant women. Therefore, you should not use Buscopan if you are pregnant.

Breast-feeding:

The passage of hyoscine butylbromide, the active substance of Buscopan, into breast milk has not been studied. Medicines of this type can prevent milk production and infants can react sensitively to such medicines. When deciding whether you should stop breast-feeding or treatment with Buscopan, your doctor must weigh up the benefit of breast-feeding to the child against the benefit of treatment to you.

Driving and using machines:

No adverse effects are normally to be expected when Buscopan is used at the intended dose. However, if symptoms such as tiredness, dizziness or impaired near-vision occur, the ability to drive and use machinery can be impaired.

Buscopan contains sucrose:

This medicinal product contains sucrose (sugar; about 41 mg per sugar-coated tablet). Please consult your doctor before taking Buscopan if you know you have an intolerance to certain sugars.

3. HOW TO TAKE BUSCOPAN

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Where not instructed otherwise by the doctor, the usual dose is: Adults and children aged 6 years and over: 1 – 2 sugar-coated tablets 3 times daily (single dose: 10 – 20 mg, maximum daily dose 60 mg hyoscine butylbromide).
Swallow the sugar-coated tablets whole with sufficient liquid. Do not take Buscopan for more than 5 days without seeking medical advice.

If you take more Buscopan than you should

Contact your doctor if you take more Buscopan than you should. The effects mentioned in section 4 can occur.

If you forget to take Buscopan:

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Many of the known side

effects are due to the anticholinergic properties of Buscopan. These anticholinergic effects are generally mild and self-limiting. The following convention is used in assessing the frequency of side effects:

Very common:	More than 1 in 10 patients treated
Common:	1 to 10 in 100 patients treated
Uncommon:	1 to 10 in 1,000 patients treated
Rare:	1 to 10 in 10,000 patients treated
Very rare:	Less than 1 in 10,000 patients treated
Not known:	Cannot be estimated from the available data

Immune system disorders:

Uncommon: skin reactions, e.g. nettle rash (urticaria), itching
Not known: breathlessness (dyspnoea), hypersensitivity reactions, severe hypersensitivity reactions that can progress to anaphylactic shock with a fall in blood pressure and a feeling of heat (hot flush).

Cardiac disorders:

Uncommon: increased heart rate

Vascular disorders:

Uncommon: fall in blood pressure, dizziness

Eye disorders:

Very rare: disorders of "near vision" (accommodation disorders), severe eye pain in glaucoma

Gastrointestinal disorders:

Uncommon: dry mouth (inhibition of salivation), diarrhoea, nausea, vomiting, upset stomach

Skin and subcutaneous tissue disorders:

Uncommon: dry skin (inhibition of sweating)

Renal and urinary disorders:

Rare: difficulty passing water, e.g. urinary retention, terminal dribbling, reduced stream

General disorders:

Uncommon: fatigue

Reporting of side effects

If you get any side effects, talk to your doctor, your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

To report any side effect(s):

- Saudi Arabia:

- The National Pharmacovigilance Centre (NPC):
- Fax : +966-11-205-7662
- SFDA Call Center: 19999
- E-mail: npc.drug@sfdagov.sa
- Website: <https://ade.sfdagov.sa>
- Sanofi- Pharmacovigilance: KSA_Pharmacovigilance@sanofi.com

- United Arab Emirates:

- Ministry of Health and Prevention/Drug Department
- Pharmacovigilance and Medical Device section
- Tel: 80011111
- E-mail: pv@mohap.gov.ae
- P.O.box: 1853 Dubai
- Dubai / United Arab Emirates

- Other countries:

- Please contact the relevant competent authority

5. HOW TO STORE BUSCOPAN

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use the medicine after the expiry date which is stated on the carton and the blister pack. The expiry date refers to the last day of that month.

Storage conditions:

Store in a safe place below 30°C.
Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Buscopan contains

- The active substance is hyoscine butylbromide.
One sugar-coated tablet contains 10 mg hyoscine butylbromide.
- The other ingredients are: sucrose, calcium hydrogen phosphate, maize starch, talc, colloidal silicon dioxide, gum Arabic, povidone, tartaric acid (Ph. Eur.), stearic acid, macrogol 6000, carnauba wax, white wax, titanium dioxide (E 171).

What Buscopan looks like and contents of the pack

Round, white, sugar-coated tablets.
BUSCOPAN sugar-coated tablets are available in original packs containing 20 or 50 tablets.
Not all pack size may be marketed in your country.

Marketing Authorization Holder

A. Nattermann & Cie. GmbH
Brünigstrasse 50
65929 Frankfurt am Main
Germany

Manufacturer

Delpharm Reims
10, rue Colonel Charbonneaux
51100 Reims, France

This leaflet was last approved in: July 2022.

Worth knowing about BUSCOPAN®

BUSCOPAN® - with a natural raw material: scopolamine from the Duboisia plant is chemically optimised to produce the well-tolerated and cramp-relieving active substance, hyoscine butylbromide. Hyoscine butylbromide relaxes knotted gastrointestinal muscles, reduces their hyperactivity and enables the natural movement processes to be restored.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to an instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists