

BUSCOPAN® AMPOULES™

Hyoscine butylbromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Buscopan.

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

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Buscopan 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 information with the medicine.

You may need to read it again.

What Buscopan is used for

Buscopan is known as an anticholinergic medicine. It relieves the pain of stomach and bowel cramps by helping your digestive system to relax. It is also used to help relax gallbladder spasms and kidney spasms, and as a diagnostic aid in radiology.

Buscopan reduces the peristalsis (wave-like contractions) of smooth

muscle resulting in relief from spasms in certain organs in the digestive system.

Your doctor may have prescribed Buscopan for another reason.

This medicine is available only with a doctor's prescription.

Before you are given Buscopan

When you must not be given it

You will only receive treatment with Buscopan ampoules if it has been prescribed for you by a doctor.

The medicine will be given to you by a healthcare professional.

Do not take Buscopan if you are allergic to hyoscine butylbromide or to any of the other 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 take Buscopan if you have:

- myasthenia gravis - a condition in which the muscles become weak and tire easily.
- glaucoma - high pressure in the eye
- porphyria – a rare blood pigment disorder
- a suspected or confirmed blockage of the bowel

- a condition where the bowel is blocked and does not work properly (paralytic or obstructive ileus). Symptoms include severe abdominal pain with lack of stools and/or nausea/vomiting
- a very enlarged bowel (megacolon)
- tachyarrhythmia – a fast heart rate
- achalasia – a condition that causes difficulty in swallowing food
- prostatic hypertrophy – prostate problems

Buscopan must not be used when there is a blockage in the stomach or bowel or in certain conditions when there is reduced bowel activity.

These conditions are best explained by your doctor or pharmacist.

Do not give it to a child under the age of 6 years.

Safety and effectiveness in children younger than 6 years have not been established.

Do not take it 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 be given this medicine, talk to your doctor.

Before you are given Buscopan

Tell your doctor immediately if your abdominal pain continues or worsens or occurs with symptoms like:

- fever
- nausea
- vomiting
- changes in bowel movements
- fainting
- blood in faeces

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

There is limited information on the use of Buscopan during pregnancy and breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Buscopan.

Taking other medicines

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

Some medicines and Buscopan may interfere with each other. These include:

- medicines used to treat or prevent nausea and vomiting such as metoclopramide
- medicines used to treat malaria such as quinine
- medicines used to treat the symptoms of Parkinson's disease such as amantadine
- medicines used to treat some mental conditions such as tri and tetracyclic antidepressants and antipsychotics
- medicines used to treat allergies such as antihistamines
- medicines for the treatment of depression, heart disease or respiratory disease such as tiotropium, ipratropium or atropine-like compounds
- any other medicine for the treatment of stomach or bowel condition

These medicines may be affected by Buscopan or may affect how well it

works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How it is given

How much to be given

Your doctor will decide what dose you will receive. This depends on your condition and other factors.

The recommended dose is one or two ampoules (20 – 40 milligrams).

The maximum dose per day is 100 milligrams (equivalent to five ampoules).

Your doctor might prescribe a different dose or duration of treatment. If you need further information, ask your doctor or pharmacist.

Do not use it for extended periods.

Worsening or persistent stomach pain should be investigated by your doctor to determine the cause of the pain.

How it is given

This medicine should only be given by a doctor or nurse and in a setting where appropriate equipment is readily available for diagnosis and patient monitoring

The injections can be given deeply into a muscle (e.g. the buttock, upper leg or upper arm) or can be given as a slow injection into the vein.

Overdose

These injections are given under medical supervision and it is very unlikely that you will be given too much.

Symptoms of an overdose may include: drowsiness, dry mouth, difficulty passing urine, reddening of the skin, decreased gastrointestinal tract movement, fast heart rate and sight disturbances.

Tell your doctor or medical staff immediately if you experience any signs of overdose.

While you are using Buscopan

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Buscopan.

Tell your doctor or pharmacist if you begin taking any other medicine while you are taking this medicine.

Tell your doctor or pharmacist if the pain is severe or does not improve within 48 hours of taking Buscopan.

Cramps in the stomach or bowel may be temporary or may signal the presence of a more serious problem.

Things to be careful of

Be careful driving or operating machinery until you know how Buscopan affects you.

This medicine may cause dizziness, tiredness, drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Do not drink alcohol while taking Buscopan.

Alcohol may increase the chance of side effects such as drowsiness.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dry mouth
- fast heart rate
- reduced sweating
- rash
- itching
- redness of the skin
- a skin condition called dyshidrosis
- difficulty with passing urine
- temporary blurred vision (due to reduced eye focusing)
- dizziness
- a drop in blood pressure
- flushing
- shortness of breath

Very rarely there have also been isolated reports of coma, hallucinations (seeing, feeling or hearing things that are not there), dystonia (unusual muscle tone causing distortion of the body), confusion, agitation and dizziness. These side effects were relieved when the patients stopped Buscopan therapy and received appropriate medical treatment.

If any of the following happen, tell your doctor immediately:

- allergic reactions (such as skin rashes, or swelling of the face and difficulty in breathing).
- sudden life-threatening allergic reactions (anaphylaxis with episodes of shortness of breath and shock)

Allergic reactions can be very serious side effects. You may need urgent medical attention or hospitalisation.

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.

Storage

Keep Buscopan ampoules in a cool dry place where the temperature stays below 30°C.

Protect from light.

Each ampoule is for single use only.

Product description

What it looks like

Buscopan 1 mL glass ampoules contain a clear, colourless solution.

Buscopan ampoules are available in packs of 5 ampoules

Ingredients

Each Buscopan ampoule contains 20 mg of hyoscine butylbromide as the active ingredient.

The ampoules also contain sodium chloride and Water for Injections.

Sponsor

Buscopan is made in Spain and supplied in Australia & New Zealand by:

Sanofi Consumer Healthcare
87 Yarraman Place
Virginia QLD 4014

Sanofi-Aventis New Zealand Limited
Level 8, 56 Cawley Street,
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