

Buscopan® Ampoules

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given Buscopan?

Buscopan contains the active ingredient hyoscine butylbromide. Hyoscine butylbromide is an anticholinergic medicine. **Buscopan is used to relieve 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.**

For more information, see Section [1. Why am I given Buscopan?](#) in the full CMI.

2. What should I know before I receive Buscopan?

Do not use if you have ever had an allergic reaction to hyoscine butylbromide or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I receive Buscopan?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking or using any other medicines including any that you get without a prescription from your pharmacy, supermarket, or health food shop. Buscopan must not be given in the muscle if you are being treated with anticoagulant medicines.

For more information see Section [3. What if I am taking or using other medicines?](#) in the full CMI.

4. How do I receive Buscopan?

- Your doctor will decide what dose you will receive and the duration of treatment.
- Buscopan is administered by a doctor or nurse. It is given by deep injection into a muscle (e.g. the buttock, upper leg or upper arm) or slow injection into a vein.

More instructions can be found in Section [4. How do I receive Buscopan?](#) in the full CMI.

5. What should I know after being given Buscopan?

Things you should do	<ul style="list-style-type: none">• Call your doctor straight away if the pain is severe or does not improve within 48 hours of being given Buscopan.• Before you take any other medicine, talk to your doctor or pharmacist.• Remind any doctor, dentist, or pharmacist you visit that you have received Buscopan.• Be careful before you drive or use any machines or tools until you know how Buscopan affects you.
Things you should not do	<ul style="list-style-type: none">• Do not drink alcohol after receiving Buscopan.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C.• Store in a cool, dry place away from moisture, heat, or sunlight.

For more information, see Section [5. What should I know after being given Buscopan?](#) in the full CMI.

6. Are there any side effects?

- Less serious side effects include redness of the skin, itching, a skin condition called dyshidrosis, rash, abnormal sweating, reduced sweating, fast heart rate, drop in blood pressure, dry mouth, flushing, difficulty with passing urine, shortness of breath, dizziness, and temporary blurred vision due to reduce eye focusing. Serious side effects are allergic reactions (such as skin rashes, or swelling of the face and difficulty in breathing) and sudden life-threatening allergic reactions (anaphylaxis with episodes of shortness of breath and shock).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Buscopan® Ampoules

Active ingredient: *hyoscine butylbromide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Buscopan. **You should also speak to your doctor, or pharmacist if you would like further information or if you have any concerns or questions about using Buscopan.**

Where to find information in this leaflet:

- [1. Why am I given Buscopan?](#)
- [2. What should I know before I am given Buscopan?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I receive Buscopan?](#)
- [5. What should I know after being given Buscopan?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given Buscopan?

Buscopan contains the active ingredient hyoscine butylbromide. Hyoscine butylbromide is an anticholinergic medicine. **Buscopan is used to relieve 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.

2. What should I know before I receive Buscopan?

Warnings

Do not receive Buscopan if:

- you are allergic to hyoscine butylbromide, or any of the 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
- Always check the ingredients to make sure you can use this medicine.
- you have myasthenia gravis - a condition in which the muscles become weak and tire easily.
- you have glaucoma - high pressure in the eye
- you have porphyria - a rare blood pigment disorder
- you have a suspected or confirmed blockage of the bowel or stomach
- you have a weakened intestinal muscles (intestinal atony)
- you have 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.
- you have a very enlarged bowel (megacolon)

- you have a fast heart rate (tachyarrhythmia)
- you have a condition that causes difficulty in swallowing food (achalasia)
- you have prostate problems - prostatic hypertrophy
- you are taking anticoagulants medicines and Buscopan will be given in the muscle

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

Check with your doctor if you:

- you have any other medical conditions
- you take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or plan to breastfeed.

3. What if I am taking other medicines?

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

Buscopan must not be given in the muscle if you are being treated with anticoagulant medicines.

Some medicines and Buscopan may interfere with each other:

- 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 conditions
- medicine used to treat certain conditions, such as disopyramide

Check with your doctor, or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Buscopan.

4. How do I receive Buscopan?

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.

If you receive too much Buscopan

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.

If you think that you have been given too much Buscopan, you may need urgent medical attention.

Tell your doctor or medical staff immediately if you feel you have been given too much Buscopan.

You should do this even if there are no signs of discomfort or poisoning.

If you experience any signs of overdose after you leave the doctor or nurse, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 if you are in Australia), or
- phone the National Poisons Information Centre (by calling 0800 POISON or 0800 764 766 if you are in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

5. What should I know after being given Buscopan?

Things you should do

Before you take any other medicine, talk to your doctor or pharmacist.

Call your doctor straight away if:

- the pain is severe or does not improve within 48 hours of being given Buscopan.

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

- you develop painful, red eye/s with loss of vision.

Remind any doctor, dentist, or pharmacist you visit that you have received Buscopan.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Buscopan affects you.

Buscopan 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.

Drinking Alcohol

Do not drink alcohol after receiving Buscopan.

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

Looking after your medicine

- Store below 30°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on windowsills.

Keep it where young children cannot reach it.

Each ampoule is for single use only.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Skin-related• Redness of the skin• Itching• A skin condition called dyshidrosis (small blisters on the hands and feet)• Rash• Abnormal sweating• Reduced sweating <p>Heart-related</p> <ul style="list-style-type: none">• Fast heart rate• Drop in blood pressure <p>Others</p> <ul style="list-style-type: none">• Dry mouth• Flushing	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • Difficulty with passing urine • Shortness of breath • Dizziness • Temporary blurred vision due to reduce eye focusing 	

Very rarely there have also been isolated reports of:

- coma,
- hallucinations (seeing, feeling, or hearing things that are not there),
- unusual muscle tone causing distortion of the body (dystonia),
- confusion,
- agitation, and
- dizziness.

These side effects were relieved when the patients stopped Buscopan therapy and received appropriate medical treatment.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Allergy-related • 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) 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Buscopan contains

Active ingredient (main ingredient)	20 mg of hyoscine butylbromide per ampoule
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • sodium chloride • water for injections
Potential allergens	Not applicable

Do not take this medicine if you are allergic to any of these ingredients.

What Buscopan looks like

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

Buscopan ampoules are available in packs of 5 ampoules.

Who distributes Buscopan

In Australia:

Sanofi Consumer Healthcare
87 Yarraman Place
Virginia QLD 4014

In New Zealand:

Sanofi-Aventis New Zealand limited
Level 8, 56 Cawley Street
Ellerslie Auckland 1051,
New Zealand

Buscopan is made in Spain.

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