

Buscopan[®] Tablets

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 taking 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.**

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

2. What should I know before I take 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 take 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.

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

4. How do I take Buscopan?

The recommended dose for adults and children over 6 years of age is two tablets four times a day taken about every 4 - 6 hours. If you no longer have any stomach pain it is not necessary to finish taking all the tablets in the pack.

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

5. What should I know after taking 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 taking Buscopan.• Before you take any other medicine, talk to your doctor or pharmacist.• Remind any doctor, dentist, or pharmacist you visit that you are taking Buscopan. |
| Things you should not do | <ul style="list-style-type: none">• Do not drink alcohol after taking Buscopan. |
| Looking after your medicine | <ul style="list-style-type: none">• Store below 25°C.• Store in a cool, dry place away from moisture, heat, or sunlight. |

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

6. Are there any side effects?

Less serious side effects include dry mouth, redness of the skin, fast heart rate, difficulty passing urine, abnormal sweating, reduced sweating.

A serious side effect is an allergic reaction with symptoms of shortness of breath, wheezing or difficulty breathing, swelling of the face, lips tongue or other parts of the body, itch, hives, or rash 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[®] Tablets

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

1. Why am I taking 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.**

2. What should I know before I take Buscopan?

Warnings

Do not take 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 fructose intolerance. Buscopan contains sucrose.
- 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 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
- 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.

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.

Children

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

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.

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

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 take Buscopan?

How much to take and how long to take it

- Follow the instructions provided and take Buscopan until your doctor tells you to stop.
- The recommended dose for adults and children over 6 years of age is two tablets four times a day taken about every 4 - 6 hours.
- If you no longer have any stomach pain it is not necessary to finish taking all the tablets in the pack.

Do not take 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 taken

Swallow the tablets whole with a glass of water.

If you forget to take Buscopan

If you miss your dose at the usual time and it is almost time for your next dose, skip the dose you missed and take your dose when you are next meant to.

Otherwise, take it as soon as you remember and then go back to taking your medicines as you normally would.

Do not take a double dose to make up for the dose you missed.

If you take too much Buscopan

If you think you have taken too much Buscopan, you may need urgent medical attention.

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.

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

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.

Do not drive a car or operate machinery if you have taken more than the recommended or prescribed dose of Buscopan.

5. What should I know after taking 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 taking Buscopan.**
Cramps in the stomach or bowel may be temporary or may signal the presence of a more serious problem.
- **your abdominal pain continues or worsens or occurs with symptoms like:**
 - fever
 - nausea
 - vomiting
 - changes in bowel movements
 - fainting
 - blood in faeces

Remind any doctor, dentist, or pharmacist you visit that you are taking Buscopan.

Drinking Alcohol

Do not drink alcohol after taking Buscopan.

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

Looking after your medicine

- Store below 25°C.
- Keep your tablets in the pack until it is time to take them.

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.

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 <p>Others</p> <ul style="list-style-type: none"> • Dry mouth • Difficulty with passing urine | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> • Allergy-related • rash, itching or hives | <p>Call your doctor straight away or go straight to the Emergency Department at your</p> |

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none"> ● swelling of the face, lips, tongue, or other parts of the body ● sudden life-threatening allergic reactions (anaphylaxis with episodes of shortness of breath and shock) | <p>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

Buscopan is available in blister packs of 10*#, 20# and 100 tablets.

*Not currently distributed in Australia

#Not available in New Zealand

Buscopan blister packs of 100 tablets are only available with a doctor's prescription.

Buscopan blister packs of 20 tablets are available only at a pharmacy in Australia.

What Buscopan contains

| | |
|---|---|
| Active ingredient (main ingredient) | 10 mg of hyoscine butylbromide per tablet |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">● Tablet Core● calcium hydrogen phosphate dihydrate● maize starch● soluble starch● colloidal anhydrous silica● tartaric acid● stearic acid Tablet Coating <ul style="list-style-type: none">● sucrose |

| | |
|----------------------------|---|
| | <ul style="list-style-type: none"> ● povidone ● purified talc ● acacia ● titanium dioxide ● macrogol 6000 ● carnauba wax ● white beeswax |
| Potential allergens | None |

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

Do not take this medicine if you have fructose intolerance. Buscopan contains sucrose.

What Buscopan looks like

Buscopan tablets are round, white, biconvex and sugar-coated (Aust R 48256).

Who distributes Buscopan

In Australia:

Sanofi Consumer Healthcare
87 Yarraman Place
Virginia QLD 4014
Australia

Toll-Free: 1800 818 806

In New Zealand:

Sanofi-Aventis New Zealand Limited

Auckland
New Zealand
Toll-free: 0800 283 684

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