

Buscopan[®] Forte Tablets

Hyoscine butylbromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Buscopan Forte tablets.

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 (Australia) and www.medsafe.govt.nz/Consumers/c_mi/CMIForm.asp (New Zealand) 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 Forte 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 Forte is used for

Buscopan Forte is known as an anticholinergic medicine. It

relieves the pain of stomach and bowel cramps by helping your digestive system to relax.

Buscopan Forte in packs of 10 tablets can be bought from a pharmacy without a doctor's prescription.

Buscopan Forte tablets are intended for the treatment of temporary complaints.

Always consult your doctor or pharmacist if the pain does not improve within 48 hours or if pain worsens after treatment.

Before you take Buscopan Forte

When you must not take it

Do not take Buscopan Forte 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 Forte if you have any conditions of galactose intolerance (for example, galactosaemia, the Lapp lactase deficiency or glucose-galactose malabsorption).

- This is because Buscopan Forte contains lactose as an ingredient.

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 Forte 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 start taking this medicine, talk to your pharmacist or doctor.

Before you start to take it

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 Forte 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 Forte.

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 Forte 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 Forte 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 to take Buscopan Forte

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The recommended dose for adults and children over 6 years of age is one tablet four times a day.

How to take it

Swallow the tablets whole with a glass of water.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it.

Do not take it for extended periods. Do not take Buscopan Forte for longer than 2-3 days at a time except on the recommendation of a doctor.

One pack of Buscopan Forte (10 tablets) is enough for 2 ½ days treatment at the recommended dose.

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

If you forget to take it

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

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

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you no longer have any stomach pain it is not necessary to finish taking all the tablets in the pack.

If you take too much (overdose)

Seek medical advice if you have used more than the recommended or prescribed

dose of Buscopan Forte.

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.

Advice can be provided by a doctor, pharmacist or Poisons Information Centre (telephone 13 11 26 in Australia and 0800 764766 in New Zealand).

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

While you are taking Buscopan Forte

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 Forte.

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 Forte.

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 Forte 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 Forte.

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 Forte.

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
- abnormal sweating
- rash
- itching
- redness of the skin
- a skin condition called dyshidrosis
- difficulty passing urine.

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 Forte therapy and received appropriate medical treatment.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency

at your nearest hospital:

- 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.

After taking Buscopan Forte

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Buscopan Forte or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can damage some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

Buscopan Forte is available in blister packs of 10 tablets.

What it looks like

Buscopan Forte tablets are white round biconvex film-coated tablets embossed with the letter 'B' on one side and the number '20' on the other side.

Buscopan Forte blister packs of 10 tablets are available only at a pharmacy.

Ingredients

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

There are also a number of other ingredients which are used in the formation of the tablet core.

These are:

- povidone
- lactose
- cellulose – microcrystalline
- magnesium stearate

The coating contains:

- proprietary ingredient Opadry II
White 85G18490

Sponsor

Buscopan Forte is made in France and supplied in Australia by:

Sanofi Consumer Healthcare
87 Yarraman Place, Virginia, Qld.
4014 Australia,

Toll-free: 1800 818 806

And in New Zealand by:
Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
New Zealand

Phone: (09) 918 5100

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