

Buscopan® Injection

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.

Keep this information while you are taking or receiving treatment with BUSCOPAN. You may need to read it again later.

To find out more about BUSCOPAN

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any concerns about receiving BUSCOPAN.

What BUSCOPAN is used for

BUSCOPAN is an anticholinergic medicine. It relieves the pain of stomach and bowel cramps by helping your digestive system to relax.

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

Ask your doctor if you have any questions about why BUSCOPAN has been prescribed for you.

Before you use it

When you must not use it

Do not take BUSCOPAN if you are allergic to hyoscine butylbromide or to any of the other ingredients in BUSCOPAN. These ingredients are listed in full at the end of this leaflet (See Ingredients). If you are uncertain as to whether you have such an allergy you should raise this concern with your doctor or pharmacist.

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

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.

Your doctor will not give BUSCOPAN injection by the intramuscular route if you are taking medicines used to prevent blood clots. In this case, your doctor may choose to give you BUSCOPAN by an intravenous route.

You should not use BUSCOPAN if the packaging is torn or shows signs of tampering.

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 use 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.

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.

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication. Special care is recommended during pregnancy, particularly in the first three months.

Breastfeeding

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication. Special care is recommended if you are breastfeeding as no studies have been conducted in nursing women.

Children

BUSCOPAN injection may be given to children under the advice of your doctor.

Ability to drive or operate machinery

In rare cases, BUSCOPAN may cause drowsiness. If affected, do not drive or operate machinery.

Alcohol

Do not drink alcohol while on medication with BUSCOPAN. Alcohol may increase the chance of side effects such as drowsiness.

How to use BUSCOPAN

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

Adults and adolescents over 12 years:

The recommended dose is one or two ampoules (20 – 40 milligrams). It can be given as a slow intravenous, intramuscular or subcutaneous injection. The maximum dose per day is 100 milligrams (equivalent to five ampoules).

Infants and young children:

The recommended dose in severe cases is 0.3 – 0.6 mg/kg bodyweight, to be administered by slow intravenous, intramuscular or subcutaneous injection several times a day. The maximum daily dose of 1.2 mg/kg should not be exceeded.

Your doctor might prescribe a different dose or duration of treatment to that described here. If you want more information, ask your doctor. BUSCOPAN injection should only be used under the supervision of a doctor and in a setting where appropriate equipment is readily available for diagnosis and patient monitoring.

If you use too much (overdose)

Overdose of BUSCOPAN injection is unlikely as it is used under medical supervision. If you do receive too much BUSCOPAN injection, signs 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 healthcare professional immediately if you experience any signs of overdose.

While you are using BUSCOPAN

Things you must do

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

As mentioned previously, do not drink alcohol. Tell your doctor or pharmacist if you begin taking any other medicine while you are taking BUSCOPAN.

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

Always consult your doctor or pharmacist if the pain is severe or does not improve within 48 hours of taking BUSCOPAN.

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.

Many of the side effects listed for BUSCOPAN are due to its anticholinergic properties. If side effects occur, they are usually mild when BUSCOPAN is used at the

recommended dose, and may disappear when you have stopped taking BUSCOPAN.

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 passing urine.
- 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).
- dizziness
- a drop in blood pressure
- flushing
- temporary blurred vision (due to reduced eye focusing)

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 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.

Unexpected effects, not listed above, can occur with any medicine. You should tell your doctor or pharmacist if you notice anything unusual, during or after taking BUSCOPAN.

After using it

Storage

BUSCOPAN injection must be stored below 30°C and protected from light. Each ampoule can be used only once and unused contents of opened ampoules must be discarded.

Disposal

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

Product Description

BUSCOPAN is the brand name of your injection.

Australian Registration number on outer carton is AUST R 17916.

What it looks like

The glass ampoules of injection contain a clear, colourless solution.

BUSCOPAN ampoules are sold to pharmacists and hospitals in packs of 5 ampoules.

Ingredients

BUSCOPAN injection contains 20 mg of hyoscine butylbromide in 1 mL of solution as the active ingredient.

The ampoules also contain sodium chloride and Water for Injections.

Sponsor

BUSCOPAN is supplied in

New Zealand by:

Sanofi-Aventis New Zealand Limited

Level 8,

56 Cawley Street Ellerslie,

Auckland

New Zealand

Tel: 0800 283 684

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