

New Zealand Consumer Medicine Information

BUSCOPAN®

Tablets and Injection

Hyoscine butylbromide

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. Do not take BUSCOPAN tablets if you have fructose intolerance. This is because BUSCOPAN tablets contain sucrose as an ingredient.

Do not take BUSCOPAN if you have myasthenia gravis, glaucoma, porphyria or a condition of the bowel known as megacolon. Seek advice from your doctor or pharmacist if you have, or have had a prostate or heart condition. This is because BUSCOPAN should not be used in some types of prostate disease and a certain type of heart complaint.

BUSCOPAN should 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.

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.

BUSCOPAN should not be used after the EXPIRY DATE on the product packaging. You should not use BUSCOPAN if the packaging is torn or shows signs of tampering.

Before you start to use it

Before you start BUSCOPAN you must tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription. In particular you should tell your doctor or pharmacist if you are taking:

- 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.

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 tablets are not recommended for use in children 6 years of age and under. 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.

Taking BUSCOPAN

Recommended Dose

Tablets

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). Tablets should be swallowed whole with a little fluid. Ask your doctor or pharmacist for further information if they have advised you to take a different dose.

Do not take BUSCOPAN for longer than 2-3 days at a time except on the recommendation of a doctor.

Injection

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 forget to take it

If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time. It is not necessary to finish taking all the tablets if you find you no longer have any pain.

Overdose

Seek medical advice if you have used more than the recommended or prescribed dose of BUSCOPAN tablets and you experience signs of overdose as listed below. Signs of 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 0800 POISON or 0800 764766). Do not drive a car or operate machinery if you have taken more than the recommended or prescribed dose of BUSCOPAN.

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

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

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

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.

BUSCOPAN tablets and injection may cause:

- dry mouth
- fast heart rate
- reduced sweating
- a skin condition called dyshidrosis
- difficulty with 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).

BUSCOPAN injection may also cause:

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

Vary 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.

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

Tablets

Leave all tablets in the pack until it is time to take a dose. The packaging protects the tablets. BUSCOPAN tablets should be kept in a cool, dry place where the temperature stays below 25°C. For example, do not leave your tablets in a car or store them in the bathroom. Heat and dampness will damage the tablets.

Keep BUSCOPAN tablets where children cannot reach them.

Injection

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

After the expiry date has passed, any unused BUSCOPAN should be returned to your pharmacist so that it can be disposed of safely.

Product Description

What the product looks like

BUSCOPAN is the brand name of your tablets and injection. The tablets are small, shiny and white in colour.

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

BUSCOPAN tablets are available in plastic bottles of 100 tablets. BUSCOPAN ampoules are sold to pharmacists and hospitals in packs of 5 ampoules.

Ingredients

Each BUSCOPAN tablet contains 10 mg of hyoscine butylbromide. There are also a number of other ingredients which are used in the formation of the tablet core. These ingredients are calcium hydrogen phosphate, maize starch, soluble starch, colloidal anhydrous silica, tartaric acid and stearic acid.

Ingredients used in the sugar coating are sucrose, povidone, purified talc, acacia, titanium dioxide, macrogol 6000, carnauba wax and white beeswax.

Each BUSCOPAN injection contains 20 mg of hyoscine butylbromide in 1mL of solution. The ampoules also contain sodium chloride and Water for Injections.

Manufacturer

BUSCOPAN is supplied in New Zealand by:
BOEHRINGER INGELHEIM (N.Z.) LIMITED
PO Box 76-216
Manukau City
Auckland
Ph 0800 802461

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