

PART III: CONSUMER INFORMATION**Buscopan®
Hyoscine Butylbromide**

This leaflet is part III of a three-part "Product Monograph" published when BUSCOPAN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BUSCOPAN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

BUSCOPAN tablets are used for the relief of smooth muscle spasm (cramps) of the gastrointestinal and genitourinary system.

BUSCOPAN ampoules are used for relief of acute genitourinary or gastrointestinal spasm, or to produce smooth muscle relaxation prior to radiological procedures where spasm may be a problem.

What it does:

Stomach cramps are caused by sudden, irregular tightening up of muscles in the wall of the intestine. BUSCOPAN works by relaxing the tight muscles, so relieving the cramps.

When it should not be used:**Do not use Buscopan if:**

- You are hypersensitive (allergic) to hyoscine butylbromide or atropines or to any of the nonmedicinal ingredients (See What the important nonmedicinal ingredients are).

Tablets:

- You have myasthenia gravis (a muscle wasting disease) untreated narrow angle glaucoma or obstructive prostatic hypertrophy (enlarged and blocked prostate).

Ampoules:

- You have myasthenia gravis, untreated narrow angle glaucoma, difficulty in urination due to inflammation of the prostate, stenotic lesions (narrowing of a duct/canal) of the gastrointestinal tract, tachycardia (fast heartbeat), angina, heart failure and megacolon (enlarged colon).

What the medicinal ingredient is:

Hyoscine butylbromide

What the important nonmedicinal ingredients are:

Tablets: acacia, carnauba wax, castor oil, lactose, magnesium stearate, maize starch, sucrose, polyethylene glycol, shellac, talc, tartaric acid, titanium dioxide, and white wax.

Ampoules: sodium chloride and water for injection

What dosage forms it comes in:

Tablets, 10 mg

Ampoules, 20 mg/mL

WARNINGS AND PRECAUTIONS

BEFORE you use BUSCOPAN talk to your doctor or pharmacist if:

- you are pregnant, likely to become pregnant or if you are breast feeding
- you are a man who suffers from prostate problems
- you have narrow angle glaucoma, megacolon or myasthenia gravis
- you have a very fast heart rate or other heart problems
- you have gut blockage problems
- you have reflux esophagitis or ulcerative colitis
- you are hypersensitive or "allergic" to hyoscine-N-butylbromide or any of the other ingredients
- you have previously been treated by a doctor for a severe sweating disorder
- you are taking antidepressants, major tranquilizers, antihistamines, antivirals, dopamine antagonists (e.g. metoclopramide) or medicines to treat heart problems

If in doubt, ask your doctor or pharmacist.

Exercise care in driving or operating machinery until you know how Buscopan may affect your vision.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with BUSCOPAN include: tricyclic antidepressants, antihistamines, quinidine, disopyramide, amantadine, MAO inhibitors, anticholinergics, dopamine antagonists such as metoclopramide, beta-adrenergic agents, antacids or adsorbent antidiarrheals.

PROPER USE OF THIS MEDICATION**Usual dose:**

Tablets: One to two 10 mg tablets per day up to a maximum of 6 tablets per day. In prolonged illness, which requires repeated dosing, one tablet 3 to 5 times a day is recommended. Swallow tablets whole with a glass of water.

Ampoules: One half (10 mg/0.5 mL) to one ampoule (20 mg/mL) administered parenterally by intramuscular, subcutaneous, or intravenous routes, at an injection rate of 1 mL/min. No dilutions of the ampoule is necessary prior to administration. The maximum dose should not exceed 100 mg/day (5 ampoules).

Overdose:

When using the product, the patient should not take more doses than directed. Particularly in the case of overdose, the side effects

listed below may be observed. In this situation, a doctor must be consulted or the Poison Control Center should be contacted immediately.

Your doctor will advise you that certain antacids or adsorbent antidiarrheals should be taken at least one hour before Buscopan.

Missed Dose:

In case a dose has been missed, take the next dose as scheduled. Do not double the dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

After taking BUSCOPAN tablets:

All medicines sometimes cause side-effects. BUSCOPAN may occasionally cause a dry mouth, blurred vision, diarrhea, nausea, reduced ability to sweat, an increase in heart rate and the inability to pass urine.

Other possible rare side-effects include, dizziness, flushing, allergic reactions (particularly skin rash and itching) and difficulty in breathing (usually in patients who suffer with asthma or allergy).

If you experience any of these effects and they persist or become troublesome, consult your doctor.

Should you suffer from a painful red eye with loss of vision, seek urgent medical advice.

If you experience any other effects not mentioned above, consult your doctor or pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking BUSCOPAN, contact your doctor or pharmacist.

HOW TO STORE IT

BUSCOPAN tablets and ampoules should be protected from light and heat.

BUSCOPAN ampoules should be protected from freezing.

Products should be stored at room temperature and are stable up to the expiration date indicated on the label.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345
 toll-free fax 866-678-6789
 By email: cadrmp@hc-sc.gc.ca

By regular mail:
 National AR Centre
 Marketed Health Products Safety and Effectiveness
 Information Division
 Marketed Health Products Directorate
 Tunney's Pasture, AL 0701C
 Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the Prescribing Information, prepared for health professionals can be found at:
<http://www.boehringer-ingenelheim.ca>
 or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at:
 1-800-263-5103 ext. 4633

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