

PRESCRIBING INFORMATION AND
PATIENT MEDICATION INFORMATION

Buscopan[®]

Hyoscine Butylbromide, Tablets

Manufacturer's Standard, 10 mg

Pr Buscopan[®]

Hyoscine Butylbromide Injection, 20 mg/mL

Antispasmodic

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Table of Contents

| | |
|---|-----------|
| PART I: HEALTH PROFESSIONAL INFORMATION..... | 3 |
| SUMMARY PRODUCT INFORMATION | 3 |
| INDICATIONS AND CLINICAL USE..... | 3 |
| CONTRAINDICATIONS | 4 |
| WARNINGS AND PRECAUTIONS..... | 4 |
| ADVERSE REACTIONS..... | 7 |
| DRUG INTERACTIONS | 8 |
| DOSAGE AND ADMINISTRATION..... | 10 |
| OVERDOSAGE | 11 |
| ACTION AND CLINICAL PHARMACOLOGY | 11 |
| STORAGE AND STABILITY..... | 13 |
| DOSAGE FORMS, COMPOSITION AND PACKAGING | 13 |
| | |
| PART II: SCIENTIFIC INFORMATION | 14 |
| PHARMACEUTICAL INFORMATION..... | 14 |
| | |
| PART III: PATIENT MEDICATION INFORMATION | 15 |
| | |
| PART III: PATIENT MEDICATION INFORMATION | 18 |

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Hyoscine Butylbromide Injection, 20 mg/mL

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

| Route of Administration | Dosage Form / Strength | Clinically Relevant Nonmedicinal Ingredients |
|--------------------------------|-------------------------------|--|
| Oral | Tablets, 10 mg | acacia, carnauba wax, castor oil, lactose, magnesium stearate, maize starch, sucrose, polyethylene glycol, shellac, talc, tartaric acid, titanium dioxide, and white wax |
| Parenteral | Ampoules, 20 mg/mL | sodium chloride and water for injection |

INDICATIONS AND CLINICAL USE

BUSCOPAN (hyoscine butylbromide) tablets are indicated for:

- The relief of smooth muscle spasm of the gastrointestinal and genitourinary systems.

BUSCOPAN ampoules are indicated for:

- The relief of acute genitourinary or gastrointestinal spasm (e.g., renal or biliary colic), or to produce smooth muscle relaxation prior to radiological procedures such as pyelography or other diagnostic procedures where spasm may be a problem (e.g., gastro-duodenal endoscopy).

Geriatrics:

No data is available.

Pediatrics:

No data is available.

CONTRAINDICATIONS

- Hypersensitivity to hyoscine butylbromide, atropinics (see WARNINGS AND PRECAUTIONS) or to any of the product excipients (See Dosage Forms, Composition and Packaging).
- BUSCOPAN (hyoscine butylbromide) tablets are contraindicated in patients with myasthenia gravis, megacolon, glaucoma or obstructive prostatic hypertrophy.
- Parenteral administration is contraindicated in patients with myasthenia gravis, untreated narrow angle glaucoma, prostatic hypertrophy with urinary retention, stenotic lesions of the gastrointestinal tract, tachycardia, angina, cardiac failure, paralytic or obstructive ileus and megacolon.
- BUSCOPAN ampoules should not be given by intramuscular injection to patients being treated with anticoagulant drugs since intramuscular hematoma may occur. In these patients, the subcutaneous or intravenous routes may be used.

WARNINGS AND PRECAUTIONS**General**

BUSCOPAN should not be taken on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

Patients intolerant of one belladonna alkaloid or derivative may also be intolerant of other belladonna alkaloids or derivatives such as hyoscine butylbromide.

After parenteral administration of BUSCOPAN, cases of anaphylaxis, including episodes of shock have been observed. As with all drugs causing such reactions, patients receiving BUSCOPAN by injection should be kept under observation.

Parenteral BUSCOPAN can cause serious and severe cardiac adverse reactions consisting of tachycardia and hypotension (see CONTRAINDICATIONS and Cardiovascular).

One sugar-coated tablet of 10 mg contains 41.2 mg sucrose, resulting in 411.8 mg sucrose per maximum recommended daily dose. Patients with the rare hereditary condition of fructose intolerance should not take this medicine.

Cardiovascular

Parenteral BUSCOPAN can cause adverse reactions of tachycardia and hypotension, which may be more serious or more severe in patients with cardiac conditions such as coronary heart disease, cardiac arrhythmias, hypertension, and mitral stenosis, and in cardiac surgery. Monitoring of these patients is advised until conditions return to normal. Emergency equipment and personnel trained in its use must be readily available.

Parenteral BUSCOPAN should be used with caution in patients with cardiac conditions. Parenteral BUSCOPAN is contraindicated in patients with tachycardia, angina, and cardiac failure (see CONTRAINDICATIONS).

The increase in heart rate may also be undesirable in patients with unstable cardiovascular status in an acute hemorrhage situation.

In addition, exercise caution in patients inclined to tachyarrhythmia.

Gastrointestinal

Exercise caution in patients with reflux esophagitis or gastrointestinal tract obstructive disease (i.e., achalasia and pyloroduodenal stenosis) due to the ability of anticholinergics/systemic antispasmodics to decrease smooth muscle motility and tone resulting in gastric retention.

Anticholinergics may aggravate hiatal hernia associated with reflux esophagitis, myasthenia gravis or pyloric obstruction.

In patients with ulcerative colitis, large anticholinergic doses may suppress intestinal motility, possibly causing paralytic ileus or resulting in obstruction; also, use may precipitate or aggravate toxic megacolon.

In case severe, unexplained abdominal pain persists or worsens, or occurs together with symptoms like fever, nausea, vomiting, changes in bowel movements, abdominal tenderness, decreased blood pressure, fainting or blood in stool, medical advice should immediately be sought

Genitourinary

BUSCOPAN (hyoscine butylbromide) tablets and ampoules should be used with caution in patients with prostatic enlargement. BUSCOPAN may precipitate or aggravate urinary retention in patients with the following conditions: non-obstructive prostatic hypertrophy, urinary retention (or the predisposition to) or obstructive uropathy such as a bladder neck obstruction due to prostatic hypertrophy (see CONTRAINDICATIONS).

Ophthalmologic

The parenteral administration of hyoscine butylbromide, particularly of higher doses, has been reported to cause transient disturbances of accommodation which recede spontaneously. Therefore, patients should be cautioned about potential visual problems and the need to exercise care while driving or operating machinery after receiving BUSCOPAN ampoules.

Therapy should be discontinued if the patient reports any unusual visual disturbances or pressure pain within the eye.

The mydriatic effect of anticholinergics/systemic antispasmodics may result in increased intraocular pressure. BUSCOPAN should be used with caution in patients with angle-closure glaucoma or with this predisposition, as anticholinergics/systemic antispasmodics may precipitate an acute angle-closure glaucoma attack (see CONTRAINDICATIONS).

Patients should seek urgent ophthalmological advice in case they should develop a painful eye with loss of vision after injection of BUSCOPAN.

Special Populations

Fertility, pregnancy and lactation:

There is limited data from the use of hyoscine butylbromide in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

There is insufficient information on the excretion of BUSCOPAN and its metabolites in human milk.

As a precautionary measure, it is preferable to avoid the use of BUSCOPAN during pregnancy and lactation.

No studies on the effects on human fertility have been conducted.

Pediatrics:

BUSCOPAN is not currently recommended for use in children.

Geriatrics:

Geriatric patients are especially susceptible to the anticholinergic side effects of constipation, dryness of mouth and urinary retention (especially in males). If these side effects continue or are severe, discontinuation of medication should be considered.

Due care is necessary when anticholinergics are administered to geriatric patients due to the danger of precipitating undiagnosed glaucoma.

Administration of anticholinergics/systemic antispasmodics to elderly patients with intestinal atony or in debilitated patients may result in obstruction.

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

However, patients should be advised that they may experience undesirable effects such as accommodation disorder or dizziness during treatment with BUSCOPAN ampoules. Therefore, caution should be recommended when driving a car or operating machinery. If patients experience accommodation disorder or dizziness, they should avoid potentially hazardous tasks such as driving or operating machinery.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Many of the listed undesirable effects can be assigned to the anticholinergic properties of BUSCOPAN. Anticholinergic side effects of BUSCOPAN are generally mild and self-limited.

Accumulated clinical and postmarketing experience indicates that the following adverse reactions can be expected with the use of BUSCOPAN:

Ampoules

Cardiac disorders

Tachycardia

Eye disorders

Visual accommodation disorders, mydriasis, increased intraocular pressure.

Gastrointestinal disorders

Xerostomia (dry mouth)

Immune system disorders

There have been very rare reports of anaphylactic reactions and anaphylactic shock including fatal outcome.

Skin reactions (e.g. urticaria, rash, erythema, pruritus), and other hypersensitivity, angioedema and fixed drug eruptions have been reported rarely.

Dyspnea

Renal and urinary disorders

Urinary retention

Skin and subcutaneous tissue disorders

Hypohidrosis, heat sensation/transpiration

Vascular disorders

There have been rare reports of dizziness, blood pressure decreased and flushing.

Tablets**Cardiac disorders**

Tachycardia

Eye disorders

Retinal pigmentation and glaucoma.

Gastrointestinal disorders

Xerostomia (dry mouth), diarrhea, nausea.

Immune system disorders

There have been very rare reports of anaphylactic reactions and anaphylactic shock.

Skin reactions (e.g. urticaria, rash, erythema, pruritus), and other hypersensitivity, angioedema and fixed drug eruptions have been reported rarely.

Dyspnea

Renal and urinary disorders

Urinary retention

Skin and subcutaneous tissue disorders

Hypohidrosis, heat sensation/transpiration

Vascular disorders

Adverse events reported during therapy with BUSCOPAN include increased pulse rate.

DRUG INTERACTIONS**Overview**

As hyoscine butylbromide can reduce the motility and secretory activity of the gastrointestinal system, the systemic absorption and pharmacologic effects of other oral medications may be delayed.

Drug-Drug Interactions

Table 1 - Established or Potential Drug-Drug Interactions

| Hyoscine Butylbromide | Effect | Clinical comment |
|---|---|--|
| Tri- and tetracyclic antidepressants Antipsychotics Atropine-like compounds | Can potentiate the anticholinergic effect. | |
| Antihistamines | Can potentiate the anticholinergic effect. | |
| Quinidine | Can potentiate the anticholinergic effect. | |
| Disopyramide | Can potentiate the anticholinergic effect. | |
| Amantadine | Can potentiate the anticholinergic effect. | |
| MAO inhibitors | May result in intensified anticholinergic side effects. Also, may block detoxification of anticholinergics thus potentiating their action. | |
| Anticholinergics | May intensify anticholinergic effects. | |
| Potassium chloride | May increase the severity of potassium chloride induced gastrointestinal lesions. | |
| Dopamine antagonists such as metoclopramide. | May result in diminution of the effects of both drugs on the gastrointestinal tract. | |
| Beta-adrenergic agents | May enhanced tachycardic effects. | |
| Antacids or adsorbent antidiarrheals | May reduce the absorption of anticholinergics, resulting in decreased therapeutic effectiveness. | Anticholinergics such as hyoscine butylbromide should be given at least one hour before these medications. |

Drug-Food Interactions

Interactions with food have not been established.

Drug-Herb Interactions

Interactions with herbs have not been established.

Drug-Laboratory Interactions

Interactions with laboratory tests have not been established.

DOSAGE AND ADMINISTRATION

Dosing Considerations

Individual response to BUSCOPAN (hyoscine butylbromide) may vary and doses should be adjusted accordingly.

Recommended Dose and Dosage Adjustment

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, 1 tablet 3 to 5 times a day is recommended.

Ampoules:

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

Missed Dose

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

Administration

Tablets should be swallowed whole with a glass of water.

The rapid action of injected BUSCOPAN is advantageous in acutely ill patients and in those situations where prompt spasmolytic activity facilitates diagnostic procedures such as radiological examinations. BUSCOPAN ampoules may also be used intramuscularly 10-15 minutes before radiological examinations of the stomach to slow peristaltic movements.

Dilution and Stability of Parenteral BUSCOPAN:

Although dilution prior to administration is not required, BUSCOPAN solution is compatible with the following solutions, should dilution be desirable:

Ringers Solution
Ringers Lactate
NaCl 0.9%
Laevulose 5%
Glucose 10%

Solutions must be mixed under sterile conditions and are stable for 8 hours.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Symptoms

Single oral doses of up to 590 mg and quantities of active drug up to 1090 mg within 5 hours have produced dry mouth, tachycardia, slight drowsiness and transient visual disorders. Other symptoms include urinary retention, reddening of the skin, and inhibition of gastrointestinal motility.

Other symptoms which occurred in animals and which may be encountered in humans include: shock, Cheyne-Stokes respiration, respiratory paralysis, clonic spasms, paresis of the striated muscle, coma, paralytic ileus and cystoparalysis.

Treatment

In the case of an oral overdose, perform gastric lavage with activated charcoal followed by magnesium sulfate (15%). BUSCOPAN overdose symptoms respond to parasympathomimetics.

For patients with glaucoma, administer pilocarpine locally. If necessary, parasympathomimetics should be administered, e.g. neostigmine 0.5-2.5 mg i.m. or i.v.. Cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis: intubation, artificial respiration.

Catheterisation may be required for urinary retention.

Other overdose symptoms should be treated with standard supportive therapy.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

BUSCOPAN (hyoscine butylbromide) is an antispasmodic agent which relaxes the smooth muscle of the gastrointestinal, biliary and urinary tracts. It is believed to act predominantly at the parasympathetic ganglia in the walls of the viscera of these organs. Structurally, BUSCOPAN exists as a quaternary ammonium compound and as a single positively charged cation throughout the entire pH range.

Pharmacokinetics

Ampoules

Absorption and distribution

After intravenous administration hyoscine butylbromide is rapidly distributed ($t_{1/2\alpha} = 4$ min, $t_{1/2\beta} = 29$ min) into the tissues. The volume of distribution (V_{ss}) is 128 L (corresponding to approx. 1.7 L/kg). Because of its high affinity for muscarinic receptors and nicotinic receptors, hyoscine butylbromide is mainly distributed on muscle cells of the abdominal and pelvic area as well as in the intramural ganglia of the abdominal organs. Plasma protein binding (albumin) of hyoscine butylbromide is approximately 4.4%. Animal studies demonstrate that hyoscine butylbromide does not pass the blood-brain barrier, but no clinical data to this effect is available. Hyoscine butylbromide (1 mM) has been observed to interact with the choline transport (1.4 nM) in epithelial cells of human placenta *in vitro*.

Metabolism and elimination

The main metabolic pathway is the hydrolytic cleavage of the ester bond. The half-life of the terminal elimination phase ($t_{1/2\gamma}$) is approximately 5 hours. The total clearance is 1.2 L/min. Clinical studies with radiolabeled hyoscine butylbromide show that after intravenous injection 42 to 61% of the radioactive dose is excreted renally and 28.3 to 37% faecally.

The portion of unchanged active ingredient excreted in the urine is approximately 50%. The metabolites excreted via the renal route bind poorly to the muscarinic receptors and are therefore not considered to contribute to the effect of the hyoscine butylbromide.

Tablets

Absorption

As a quaternary ammonium compound, hyoscine butylbromide is highly polar and hence only partially absorbed following oral (8%) or rectal (3%) administration. After oral administration of single doses of hyoscine butylbromide in the range of 20 to 400 mg, mean peak plasma concentrations between 0.11 ng/mL and 2.04 ng/mL were found at approximately 2 hours. In the same dose range, the observed mean AUC_{0-tz} -values varied from 0.37 to 10.7 ng h/mL. The median absolute bioavailabilities of different dosage forms, i.e. coated tablets, suppositories and oral solution, containing 100 mg of hyoscine butylbromide each were found to be less than 1%.

Distribution

Because of its high affinity for muscarinic receptors and nicotinic receptors, hyoscine butylbromide is mainly distributed on muscle cells of the abdominal and pelvic area as well as in the intramural ganglia of the abdominal organs. Plasma protein binding (albumin) of hyoscine butylbromide is approximately 4.4%. Animal studies demonstrate that hyoscine butylbromide does not pass the blood-brain barrier, but no clinical data to this effect is available. Hyoscine butylbromide (1 mM) has been observed to interact with the choline transport (1.4 nM) in epithelial cells of human placenta *in vitro*.

Metabolism and elimination

Following oral administration of single doses in the range of 100 to 400 mg, the terminal elimination half-lives ranged from 6.2 to 10.6 hours. The main metabolic pathway is the hydrolytic cleavage of the ester bond. Orally administered hyoscine butylbromide is excreted in the faeces and in the urine. Studies in man show that 2 to 5% of radioactive doses is eliminated renally after oral, and 0.7 to 1.6% after rectal administration. Approximately 90% of recovered radioactivity can be found in the faeces after oral administration. The urinary excretion of hyoscine butylbromide is less than 0.1% of the dose. The mean apparent oral clearances after oral doses of 100 to 400 mg range from 881 to 1420 L/min, whereas the corresponding volumes of distribution for the same range vary from 6.13 to 11.3 x 10⁵ L, probably due to very low systemic availability.

The metabolites excreted via the renal route bind poorly to the muscarinic receptors and are therefore not considered to contribute to the effect of the hyoscine butylbromide.

STORAGE AND STABILITY

BUSCOPAN tablets and ampoules should be protected from light and heat. BUSCOPAN ampoules should be protected from freezing. Products should be stored at 15 – 30°C and are stable up to the expiration date indicated on the label.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage Forms

Tablets: Round, white, sugar-coated tablets each containing 10 mg of hyoscine butylbromide.

Ampoules: Containing 20 mg of hyoscine butylbromide in 1 mL aqueous solution.

Composition

Tablets: hyoscine-N-butylbromide. Non-medicinal ingredients include acacia, carnauba wax, castor oil, lactose, magnesium stearate, maize starch, sucrose, polyethylene glycol, shellac, talc, tartaric acid, titanium dioxide, and white wax.

Ampoules: hyoscine-N-butylbromide. Non-medicinal ingredients include sodium chloride and water for injection.

Packaging

Tablets: Bottles of 100 tablets. Blister packages of 10 and 20 tablets.

Ampoules: Packages of 10 ampoules.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: hyoscine butylbromide

Chemical name: (1S,3S,5R,6R,7S)-8-Butyl-6,7-epoxy-3-[(S)-tropoyloxy] tropanium bromide

Molecular formula and molecular mass: C₂₁H₃₀BrNO₄, 440.4

Physicochemical properties: A white or almost white, odourless or almost odourless, crystalline powder, soluble 1 to 1 in water, 1 in 50 of alcohol, and 1 in 5 of chloroform. A 10% solution in water has a pH of 5.5 to 6.5.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

**Pr Buscopan®
Hyoscine Butylbromide Injection**

Read this carefully before you start taking BUSCOPAN. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about BUSCOPAN.

What are BUSCOPAN Ampoules used for?

- For the relief of smooth muscles spasms in the stomach, gut, bladder or uterus.
- To relax the smooth muscles of the stomach, gut or urinary tract before medical tests.

How do BUSCOPAN Ampoules work?

- Cramps are caused by sudden, strong tightening of muscles.
- This drug relaxes the tight muscles of the stomach, intestines, bladder or uterus and relieves the cramps.

What are the ingredients in BUSCOPAN Ampoules?

Medicinal ingredient: Hyoscine butylbromide.

Non-medicinal ingredients: Sodium chloride and water for injection.

BUSCOPAN comes in the following dosage forms:

Ampoules, 20 mg/mL hyoscine butylbromide.

Tablets, 10 mg hyoscine butylbromide.

Do not use BUSCOPAN Ampoules if you:

- are allergic to:
 - hyoscine butylbromide.
 - atropinics.
 - any of the ingredients in the product (see list in **What are the ingredients in BUSCOPAN Ampoules**).
- are taking this drug by injection into the muscle and you are taking blood thinners (anticoagulants). Taking the drugs at the same time may cause bleeding in the muscle.
- have any of the below conditions:
 - muscle wasting disease (myasthenia gravis).
 - untreated high pressure inside of your eye (closed-angle glaucoma).
 - problems with urination due to prostate issues.
 - narrowing parts of the gastrointestinal tract (stenosis).
 - fast heartbeat (tachycardia).
 - heart failure.
 - chest pain and short breath (angina).
 - your intestine stopped working or may be blocked.
 - enlarged bowel (megacolon).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BUSCOPAN. Talk about any health conditions or problems you may have, including if you:

- are pregnant or plan to become pregnant, breastfeeding or plan to breastfeed.
 - you should not use this drug if you are pregnant or breastfeeding.
- are a man and have prostate problems.
- have stomach acid backing up in your throat (reflux-esophagitis).
- have inflamed bowels (e.g. ulcerative colitis).
- contact your doctor immediately if you suffer the following:
 - sudden or severe stomach pain with other symptoms such as:
 - fever.
 - nausea.
 - vomiting.
 - blood in the stool.
 - low blood pressure (e.g. light-headedness).

Do not drive or operate machinery if you suffer:

- dizziness.
- blurred vision.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may interact with BUSCOPAN:

- | | |
|---|---|
| • Amantadine. | • Dopamine antagonists (e.g. metoclopramide). |
| • Anticholinergics (e.g. ipratropium, atropine). | • Heart medications (e.g. disopyramide, quinidine). |
| • Antihistamines (e.g. diphenhydramine, hydroxyzine). | • MAO inhibitors (e.g. moclobemide, selegiline, tranylcypromine, phenelzine). |
| • Beta-adrenergic agents (e.g. salbutamol). | • Tricyclic antidepressants (e.g. amitriptyline, doxepin). |

If you are taking antacids or adsorbent anti-diarrheals, your healthcare professional may tell you to take them at least 1 hour before taking this drug.

How to take BUSCOPAN Ampoules:

Usual dose (Adults):

Administer one-half (10 mg/0.5 mL) to 1 ampoule (20 mg/mL) at an injection rate of 1 mL/min by one of the following routes:

- intramuscular.
- subcutaneous.
- intravenous.

No dilution of ampoule is needed. The maximum dose should not exceed 100 mg/day (5 ampoules).

What are the possible side effects from using BUSCOPAN Ampoules?

This drug may sometimes cause:

- dry mouth.
- feeling hot and decreased sweating.
- increased heart rate.
- not being able to pass urine.
- increase fluid pressure inside of the eyes.
- other rare side effects may occur such as:
 - dizziness.
 - flushing.
 - allergic reactions (skin rash, itching).
 - skin reactions (e.g. hives, rash, skin redness, itching).
 - rapid swelling of the skin and skin tissue (angio-edema).
 - decreased blood pressure.
 - difficulty in breathing (usually in patients who suffer with asthma or allergy).

There have been very rare reports of severe, allergic reactions and severe allergic shock including death.

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

If you experience any of these effects which persist or become troublesome or any side effects not listed here, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Protect from freezing, light and heat. Store at room temperature (15 - 30°C). Product is stable up to the labelled expiry.

Keep out of reach and sight of children.

If you want more information about BUSCOPAN:

- Talk to your healthcare professional.
- Find the full Prescribing Information that is prepared for healthcare professionals by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); or by contacting the sponsor, sanofi-aventis Canada Inc., by visiting www.sanofi.ca or by calling **1-800-265-7927**.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last revised: December 1, 2017

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PATIENT MEDICATION INFORMATION

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Hyoscine Butylbromide Tablets**

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What are BUSCOPAN Tablets used for?

- For the relief of smooth muscles spasms in the stomach, gut, bladder or uterus.

How do BUSCOPAN Tablets work?

- Cramps are caused by sudden, strong tightening of muscles.
- This drug relaxes the tight muscles of the stomach, intestines, bladder or uterus and relieves the cramps.

What are the ingredients in BUSCOPAN Tablets?

Medicinal Ingredient: Hyoscine butylbromide.

Non-medicinal Ingredients: Acacia, carnauba wax, castor oil, lactose, magnesium stearate, maize starch, sucrose, polyethylene glycol, shellac, talc, tartaric acid, titanium dioxide and white wax.

BUSCOPAN comes in the following dosage forms:

Tablets, 10 mg hyoscine butylbromide.

Ampoules, 20 mg/mL hyoscine butylbromide.

Do not use BUSCOPAN Tablets if you:

- are allergic to:
 - hyoscine butylbromide.
 - atropinics.
 - any of the ingredients in the product (see list in **What are the ingredients in BUSCOPAN Tablets**).
- have any of the below conditions:
 - muscle wasting disease (myasthenia gravis).
 - untreated high pressure inside of your eye (closed-angle glaucoma).
 - problems with urination due to prostate issues.
 - enlarged bowel (megacolon).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BUSCOPAN. Talk about any health conditions or problems you may have, including if you:

- are pregnant or plan to become pregnant, breastfeeding or plan to breastfeed.
 - you should not use this drug if you are pregnant or breastfeeding.
- are a man and have prostate problems.
- have stomach acid backing up in your throat (reflux-esophagitis).
- have inflamed bowels (e.g. ulcerative colitis).
- have a fructose (a sugar) or lactose intolerance you should not take this medication.
- contact your doctor immediately if you suffer the following:
 - sudden or severe stomach pain with other symptoms such as:
 - fever.
 - nausea.
 - vomiting.
 - blood in the stool.
 - low blood pressure (e.g. light-headedness).

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may interact with BUSCOPAN:

- Amantadine.
- Anticholinergics (e.g. ipratropium, atropine).
- Antihistamines (e.g. diphenhydramine, hydroxyzine).
- Beta-adrenergic agents (e.g. salbutamol).
- Dopamine antagonists (e.g. metoclopramide).
- Heart medications (e.g. disopyramide, quinidine).
- MAO inhibitors (e.g. moclobemide, selegiline, tranylcypromine, phenelzine).
- Tricyclic antidepressants (e.g. amitriptyline, doxepin).

If you are taking antacids or adsorbent anti-diarrheals, your healthcare professional may tell you to take them at least 1 hour before taking this drug.

How to take BUSCOPAN Tablets:

Usual dose (Adults):

- Take 1 to 2 tablets per day. Do not take more than 6 tablets per day.
- In prolonged illness, the doctor may recommend taking one tablet 3 to 5 times a day. Do not take more than directed.
- Swallow tablets whole with a glass of water.

Overdose:

If you think you have taken too much BUSCOPAN, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

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

What are the possible side effects from using BUSCOPAN Tablets?

This drug may sometimes cause:

- dry mouth.
- feeling hot and decreased sweating.
- increased heart rate.
- not being able to pass urine.
- increase fluid pressure inside of the eyes.
- other rare side effects such as:
 - allergic reactions (skin rash and itching).
 - skin reactions (e.g. hives, rash, skin redness, itching).
 - rapid swelling of the skin and skin tissue (angio-edema).
 - difficulty in breathing (usually in patients who suffer with asthma or allergy).

There have been very rare reports of severe, allergic reactions and severe allergic shock.

If you experience any of these effects which persist or become troublesome or any side effects not listed here, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Protect from light and heat. Store at room temperature (15 - 30°C). Product is stable up to the labelled expiry.

Keep out of reach and sight of children.

If you want more information about BUSCOPAN:

- Talk to your healthcare professional.
- Find the full Prescribing Information that is prepared for healthcare professionals by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); or by contacting the sponsor, sanofi-aventis Canada Inc., by visiting www.sanofi.ca or by calling **1-800-265-7927**.

This leaflet was prepared by sanofi-aventis Canada Inc.

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