

Hyoscine N-butylbromide

Buscopan®



sanofi

WHAT IS HYOSCINE-N-BUTYLBROMIDE (Buscopan®)?

It is an antispasmodic used for gastrointestinal tract spasm, spasm and dyskinesia of the biliary system and genitourinary tract spasm.

WHAT IS CONTAINED IN HYOSCINE-N-BUTYLBROMIDE (Buscopan®)?

1 sugar coated (s.c.) tablet contains10 mg Hyoscine-N-butylbromide

Excipients: dibasic calcium phosphate, maize starch, starch soluble, aerosil 200, tartaric acid, stearic acid, polyvidone, saccharose, talc, acacia, titanium dioxide, polyethylene glycol 6000, carnauba wax, beeswax white

HOW DOES HYOSCINE-N-BUTYLBROMIDE (Buscopan®) WORK?

The active ingredient in Buscopan is Hyoscine-N-butylbromide, a known antispasmodic substance. It relieves the pain by acting on the muscle spasm which causes the pain.

HOW MUCH HYOSCINE-N-BUTYLBROMIDE (Buscopan®) SHOULD BE TAKEN?

Unless otherwise prescribed by your physician, the following doses are recommended:

Adults and children over 6 years:

1 - 2 sugar coated tablets 3 - 5 times daily
The tablets should be swallowed whole with adequate fluid.
Hyoscine-N-butylbromide (Buscopan®) should not be taken

on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

WHO CANNOT TAKE HYOSCINE-N-BUTYLBROMIDE (Buscopan®)?

Hyoscine-N-butylbromide (Buscopan®) is contraindicated in:

- patients who have demonstrated prior hypersensitivity to Hyoscine-N-butylbromide or any other component of the product
- myasthenia gravis
- mechanical stenosis in the gastrointestinal tract
- paralytical or obstructive ileus
- megacolon
- narrow angle glaucoma

In case of rare hereditary conditions that may be incompatible with an excipient of the product, the use of the product is contraindicated.

Such special warnings and precautions include the following:

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 be immediately sought.

Buscopan 10 mg Tablets should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery where it may further accelerate the heart rate. Due to the risk of anticholinergic complications, caution should be used in patients susceptible to intestinal or urinary outlet obstructions.

Because of the possibility that anticholinergics may reduce sweating, Buscopan should be administered with caution to

Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as Buscopan in patients with undiagnosed and therefore untreated narrow angle glaucoma. Therefore, patients should seek urgent ophthalmological advice in case they should develop a painful, red eye with loss of vision whilst or after taking Buscopan. One sugar coated tablet of 10 mg contains 41.2 mg sucrose. Patients with the hereditary condition of fructose intolerance should not take this medicine.

No studies on the effects on the ability to drive and use machines have been performed. Because of possible visual accommodation disturbances patients should not drive or operate machinery if affected.

WHAT IS THE EFFECT OF GIVING HYOSCINE-N-BUTYLBROMIDE (Buscopan®) TOGETHER WITH OTHER MEDICATIONS?

Tell your physician if you begin taking any other medicine while you are taking Hyoscine-N-butylbromide (Buscopan®).

The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antihistamines, antipsychotics, quinidine, amantadine, disopyramide and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by Hyoscine-N-butylbromide (Buscopan®).

Concomitant treatment with dopamine antagonists such as metoclopramide may result in diminution of the effects of both drugs on the gastrointestinal tract.

The tachycardic effects of beta-adrenergic agents may be enhanced by Hyoscine-N-butylbromide (Buscopan®).

CAN HYOSCINE-N-BUTYLBROMIDE (Buscopan®) BE USED DURING PREGNANCY AND LACTATION?

Pregnancy

There are limited data from the use of hyoscine butylbromide in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). As a precautionary measure Hyoscine-N-butylbromide (Buscopan®) is not recommended during pregnancy.

Lactation

There is insufficient information on the excretion of hyoscine butylbromide and its metabolites in human milk. A risk to the breastfeeding child cannot be excluded. Use of Buscopan during breastfeeding is not recommended.

Fertility

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

WHAT ARE THE POSSIBLE SIDE EFFECTS OF HYOSCINE-N-BUTYLBROMIDE (Buscopan®)?

Many of the listed undesirable effects can be assigned to the anticholinergic properties of Hyoscine-N-butylbromide (Buscopan®).

Anticholinergic side effects of Hyoscine-N-butylbromide (Buscopan®) are generally mild and self-limited. Adverse events have been ranked under headings of frequency using the following convention:

Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1000$ to $< 1/100$); rare ($\geq 1/10000$ to $< 1/1000$); very rare ($< 1/10000$); not known (cannot be estimated from the available data).

Immune system disorders

Not known*: anaphylactic shock, anaphylactic reactions, dyspnoea, and other hypersensitivity

Cardiac disorders
Uncommon: tachycardia
Skin and subcutaneous tissue disorders
Uncommon: skin reactions (e.g. urticaria, pruritus), abnormal sweating
Not known*: rash, erythema
Renal and urinary disorders
Rare: urinary retention

* This adverse reaction has been observed in post-marketing experience. With 95% certainty, the frequency category is not greater than uncommon (3/1,368) but might be lower. A precise frequency estimation is not possible as the adverse drug reaction did not occur in a clinical trial database of 1,368 patients.

Overdose

Symptoms

In case of overdose, anticholinergic effects such as urinary retention, dry mouth, reddening of the skin, tachycardia, inhibition of gastrointestinal motility and transient visual disturbances may occur, and Cheynes-Stokes respiration has been reported.

Therapy

In the case of oral poisoning, gastric lavage with medicinal charcoal should be followed by magnesium sulfate (15%). Symptoms of Buscopan overdosage respond to parasympathomimetics. For patients with glaucoma, pilocarpine should be given locally. Cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis, intubation and artificial respiration should be considered. Catheterisation may be required for urinary retention. In addition, appropriate supportive measures should be used as required.

HOW IS HYOSCINE-N-BUTYLBROMIDE (Buscopan®) AVAILABLE?

Buscopan®, is available in:
Sugar-coated tablets 10 mg Pack of 120's
Ampoules 20 mg/1 mL* Pack of 10's
*Caution: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription

REPORTING OF SIDE EFFECTS OR ANY SUSPECTED ADVERSE EVENT

For suspected adverse drug reactions, report to www.fda.gov.ph and CHCPV@sanofi.com. Patients should seek medical attention immediately at the first sign of any adverse drug reaction.

By reporting side effects, you can help provide more information on the safety of this product.
Store at temperatures not exceeding 30°C.

Manufactured by:

SANOVI VIETNAM SHAREHOLDING COMPANY
Lot I-8-2, D8 Road, Saigon Hi-Tech Park, Long Thanh My Ward,
Thu Duc City, Ho Chi Minh City, Vietnam

*Manufactured by:

Sanofi Ilac Sanayi Ve Ticaret Anonim Sirketi
Kucukkaristiran Mahallesi, Merkez Sokak, No: 223/A,
Buyukkaristiran, Luleburgaz, Kirklareli, Turkey

Imported by:

Opella Healthcare Philippines, Inc.
21st and 22nd Floors, One World Place Corporate Offices,
32nd St., Bonifacio Global City, Taguig City

*T. M. Reg. Phil. Pat. Off.

DR-XY41205 (10 mg Sugar-coated Tablet)
Date of first authorization: 08 August 2013
DR-4184 (20 mg/1 mL Ampoule)

Date of first authorization: 01 April 1962

Date of Revision of Patient Information Leaflet: July 2023

Store in a safe place out of the reach of children!

923391