

BUSCOPAN
Tablets and Ampoules
BUSCOPAN FORTE
Tablets

DESCRIPTION

Proprietary Name Buscopan

Approved Name Hyoscine butylbromide

Buscopan ampoules also contain sodium chloride and distilled water.

Buscopan tablets are available in two strengths:

- Buscopan tablets 10 mg hyoscine butylbromide per tablet. Buscopan tablets also contain calcium hydrogen phosphate, maize starch, soluble starch, colloidal anhydrous silica, tartaric acid, stearic acid and, in the tablet coating, sucrose, povidone, purified talc, acacia, titanium dioxide, macrogol 6000, carnauba wax and white beeswax.
- Buscopan Forte tablets contain 20 mg hyoscine butylbromide per tablet. Buscopan Forte tablets also contain povidone, lactose, cellulose - microcrystalline, magnesium stearate and Opadry II white 85G18490.

PHARMACOLOGY

Buscopan is a quaternary ammonium compound which, as an anticholinergic agent, has a ganglion blocking component. Due to its anticholinergic action, Buscopan reduces the tone and peristalsis of smooth muscle in hollow organs with parasympathetic innervation. As a quaternary ammonium compound with low lipid solubility, it cannot pass the blood/brain barrier easily and only rarely causes the central nervous system side effects associated with atropine and hyoscine.

Buscopan is a spasmolytic. The anticholinergic spasmolytic effect is based both on competitive inhibition of the parasympathetic activation of smooth muscle mediated through muscarinic receptors and, more markedly, through ganglionic blockade of neural transmission.

Buscopan is a powerful smooth muscle relaxant, effective when given by mouth or by injection. In the recommended dosages, Buscopan relieves smooth muscle spasm rapidly. Undesirable 'atropine-like' side effects such as blurred vision, palpitation or dry mouth are rare.

Pharmacokinetics

Buscopan is poorly absorbed from the gastrointestinal tract and is rapidly distributed. The bioavailability of oral Buscopan, as calculated from plasma levels, is reported to be 0.13%. Upon oral administration hyoscine butylbromide concentrates especially in the tissue of the gastrointestinal tract, liver and kidneys. The high affinity of this agent to the tissue is reflected by the very short half-life, $t_{1/2}$ of 3 minutes (distribution phase) of the blood

levels, while the excretion rates are slow. Thus, in spite of the extremely low blood levels measurable over a short period of time, hyoscine butylbromide remains available at the site of action in the tissue in high concentrations.

INDICATIONS

Buscopan and Buscopan Forte tablets Spasm of the gastrointestinal tract.

Buscopan ampoules Spasm of the gastrointestinal tract, biliary spasm, renal spasm, diagnostic aid in radiology.

CONTRAINDICATIONS

Buscopan are contraindicated in patients with:

- known hypersensitivity to hyoscine butylbromide or to any of the excipients of Buscopan (excipients are listed under DESCRIPTION)
- mechanical stenoses of the gastrointestinal tract
- achalasia
- paralytic ileus
- intestinal atony
- prostatic hypertrophy with urinary retention
- myasthenia gravis
- glaucoma
- pathological tachyarrhythmias
- megacolon

Buscopan should not be given to patients with porphyria as, according to a single report, it has been said to exacerbate the disease.

By intramuscular injection, Buscopan ampoules are contraindicated in patients being treated with anticoagulant drugs as intramuscular haematoma may occur. In these patients, intravenous routes may be used.

Buscopan and Buscopan Forte tablets should not be used in patients with rare hereditary conditions that may be incompatible with the tablet excipients (see Precautions).

PRECAUTIONS

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.

Hyoscine may cause drowsiness: patients so affected should not drive or operate machinery. Patients should abstain from alcohol. However, as a quaternary ammonium compound with low lipid solubility, Buscopan cannot cross the blood/brain barrier easily and only rarely causes the central nervous system side effects associated with atropine and hyoscine.

After parenteral administration of Buscopan, patients with visual accommodation disturbances should not drive or operate machinery until vision has normalised.

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. Patients should be advised to seek urgent ophthalmological advice if they develop a painful, red eye with loss of vision after an injection of Buscopan.

After parenteral administration, 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.

One Buscopan tablet contains 41.2 mg sucrose, resulting in 392.6 mg sucrose per maximum recommended daily dose. Patients with the rare hereditary condition of fructose intolerance should not take this medicine.

One Buscopan Forte tablet contains 138.5 mg lactose, resulting in 554 mg lactose per maximum recommended daily dose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, the Lapp lactose deficiency or glucose-galactose malabsorption, should not take this medicine.

Use in Pregnancy (Category B2)

There is limited data from the use of hyoscine butylbromide in pregnant women. As a precautionary measure, it is preferable to avoid the use of BUSCOPAN[®] during pregnancy.

Use in Lactation

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 lactation.

Interactions with other drugs

The anticholinergic effects of drugs such as amantadine, tri- and tetracyclic antidepressants, quinidine, antihistamines, antipsychotics, disopyramide, phenothiazines, belladonna alkaloids, other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) and MAO inhibitors etc, together with the tachycardia induced by beta-sympathomimetics, can be potentiated by Buscopan.

The concomitant administration of dopamine antagonists, such as metoclopramide, can reciprocally antagonise the effect on gastrointestinal tract motility.

ADVERSE REACTIONS

Many of the listed adverse effects of Buscopan can be attributed to its anticholinergic properties. Anticholinergic side effects of Buscopan are generally mild and self limited.

Immune system disorders

Tablets: Anaphylactic reactions with episodes of dyspnoea and anaphylactic shock, skin reactions (e.g. urticaria, rash, erythema, pruritus), facial and periorbital swelling and other hypersensitivity reactions.

Ampoules: Anaphylactic shock including fatal outcome, anaphylactic reactions, dyspnoea, skin reactions (e.g. urticaria, rash, erythema, pruritus) and other hypersensitivity reactions.

Eye disorders

Ampoules: Accommodation disorders, mydriasis, increased intraocular pressure

Cardiac Disorders

Tablets and Ampoules: Tachycardia

Vascular disorders

Ampoules: Decreased blood pressure, dizziness and flushing

Gastrointestinal disorders

Tablets and Ampoules: Dry mouth

Skin and subcutaneous tissue disorders

Tablets and Ampoules: Dyshidrosis

Renal and urinary disorders

Tablets and Ampoules: Impaired micturition

Very rarely in the national post marketing surveillance data base, there have been isolated reports following parenteral administration of coma, hallucinations, dystonia, confusion, agitation and dizziness from which the patient recovered after drug withdrawal and appropriate treatment. In very rare cases, dyspnoea has been reported.

DOSAGE AND ADMINISTRATION

Tablets

Adults and children over 6 years: 2 Buscopan tablets (2 x 10mg) four times daily. OR
1 Buscopan Forte tablet (1 x 20 mg) four times daily

Buscopan tablets are not recommended for children under 6 years of age.

Ampoules

1 or 2 ampoules (20 or 40mg) by intramuscular or slow intravenous injection.
A maximum daily dose of 100mg should not be exceeded.

BUSCOPAN[®] tablets and ampoules should not be taken on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

OVERDOSAGE

In case of overdose, advice can be obtained from the Poisons Information Centre (telephone 13 11 26).

Symptoms

Serious signs of poisoning have not been observed in man. In case of overdose, anticholinergic symptoms such as urinary retention, dry mouth, reddening of the skin, inhibition of gastrointestinal motility, tachycardia, drowsiness and transient visual disorders may occur.

Toxicity data from studies in animals after parenteral administration suggest that the following may be possible: shock, Cheyne-Stokes respiration, respiratory paralysis, clonic spasms, paralysis of striated muscle, coma, paralytic ileus, bladder atony.

Management

After oral overdose, induce emesis, gastric lavage, activated charcoal followed by magnesium sulfate (15%). Supportive measures if necessary should be instituted. Symptoms of overdosage may respond to parasympathomimetics. Ophthalmological advice should be sought urgently in cases of glaucoma. Pilocarpine may be administered locally in patients with glaucoma. Sympathomimetics may be used for circulatory support. For mental excitation, diazepam.

In case of respiratory paralysis, intubation and assisted respiration. Catheterisation may be required for urinary retention.

PRESENTATION

Buscopan Tablets each containing 10mg
Blister packs of 20 and 100

Buscopan Forte Tablets each containing 20 mg
Blister packs of 10

Ampoules (1mL) each containing 20mg
Boxes of 5

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