

# **BUSCOPAN<sup>®</sup> Ampoules**

## **Hyoscine-N-butylbromide**

### **Composition**

1 ampoule of 1 ml contains 20.0 mg  
Hyoscine-N-butylbromide

Excipients: Sodium chloride, Water for injection

### **Product Description**

Colourless glass ampoules containing colourless or almost colourless solution free of visible particles.

### **Indications**

Acute gastro-intestinal, biliary, and genito-urinary spasm, including biliary and renal colic. As an aid in diagnostic and therapeutic procedures, where spasm may be a problem, e.g. gastro-duodenal endoscopy, and in radiology.

### **Dosage and Administration**

#### **Adults and adolescents over 12 years:**

1 - 2 ampoules of BUSCOPAN (20 - 40 mg) may be administered by slow intravenous, intramuscular injection several times daily.

The maximum daily dose of 100 mg should not be exceeded.

BUSCOPAN<sup>®</sup> ampoules should not be taken on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

### **Contraindications**

BUSCOPAN<sup>®</sup> ampoules are contraindicated in:

- Patients who have demonstrated prior hypersensitivity to Hyoscine butylbromide or any other component of the product
- Untreated narrow angle glaucoma
- Hypertrophy of the prostate with urinary retention
- Mechanical stenosis in the gastrointestinal tract
- Tachycardia
- Paralytical or obstructive ileus
- Megacolon
- Myasthenia gravis

By intramuscular injection, BUSCOPAN<sup>®</sup> ampoules are contraindicated:

- 
- in patients being treated with anticoagulant drugs since intramuscular haematoma may occur. In these patients, the subcutaneous or intravenous routes may be used.

### **Special Warnings and 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, appropriate diagnostic measures are needed to investigate the etiology of the symptoms.

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 after the injection of BUSCOPAN®.

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.

Caution is needed in patients with cardiac conditions submitted to parenteral treatment with BUSCOPAN®. Monitoring if these patients is advised.

### **Interactions**

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 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 BUSCOPAN®.

### **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 (please refer to “toxicology”).

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 (please refer to “toxicology”).

### **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.

### **Side effects**

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.

#### Immune system disorders

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

#### Eye disorders

Accommodation disorders, mydriasis, increased intraocular pressure.

#### Cardiac disorders Tachycardia

#### Vascular disorders

Blood pressure decreased , dizziness , flushing.

#### Gastrointestinal disorders

Dry mouth

#### Skin and subcutaneous tissue disorders

Dyshidrosis

#### Renal and urinary disorders

Urinary retention

### **Reporting of suspected adverse reactions**

Report immediately if you experience any adverse reaction or undesirable condition during and after using the medicinal product to [farmakovigilans@kalventis.com](mailto:farmakovigilans@kalventis.com).

### **Overdose**

#### Symptoms

In the case of overdose, anticholinergic effects may be observed.

#### Therapy

If required, parasympathomimetic drugs should be administered. Ophthalmological advice should be sought in cases of glaucoma urgently. Cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis: intubation, artificial respiration should be considered. Catheterisation may be required for urinary retention. In addition, appropriate supportive measures should be used as required.

### **Pharmacological properties**

BUSCOPAN® exerts a spasmolytic action on the smooth muscle of the gastro-intestinal, biliary and genito-urinary tracts. As a quaternary ammonium derivative, hyoscine butylbromide does not enter the central nervous system. Therefore, anticholinergic side effects at the central nervous system do not occur. Peripheral anticholinergic action results from a ganglion-blocking

action within the visceral wall as well as from an anti- muscarinic activity.

## **Pharmacokinetics**

### 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.

## **Toxicology**

Acutely, hyoscine butylbromide has a low index of toxicity: oral LD<sub>50</sub> values were 1000- 3000 mg/kg in mice, 1040-3300 mg/kg in rats, and 600 mg/kg in dogs. Toxic signs were ataxia and decreased muscle tone, additionally, in mice tremor and convulsions, in dogs mydriasis, dry mucous membranes and tachycardia. Deaths from respiratory arrest occurred within 24 h. The intravenous LD<sub>50</sub> values of hyoscine butylbromide were 10-23 mg/kg in mice and 18 mg/kg in rats.

In repeated oral dose toxicity studies over 4 weeks, rats tolerated 500 mg/kg = "no observed adverse effect level (NOAEL)". At 2000 mg/kg, by the action on parasympathetic ganglia of visceral area, hyoscine butylbromide paralysed the gastrointestinal function resulting in obstipation. Eleven out of 50 rats died. Haematology and clinical chemistry results did not show dose-related variations.

Over 26 weeks, rats tolerated 200 mg/kg, while at 250 and 1000 mg/kg, the gastro-intestinal function was depressed and deaths occurred. The NOAEL of the 39-week oral (capsule) dog study was 30 mg/kg. The majority of clinical findings was attributable to acute effects of hyoscine butylbromide at high dosages (200 mg/kg). No adverse histopathological findings were observed.

A repeated intravenous dose of 1 mg/kg was well tolerated by rats in a 4-week study. At 3 mg/kg, convulsions occurred immediately after injection. Rats dosed with 9 mg/kg died from respiratory paralysis.

Dogs treated intravenously over 5 weeks at 2 x 1, 2 x 3 and 2 x 9 mg/kg, showed a dose-dependent mydriasis in all treated animals, in addition at 2 x 9 mg/kg, ataxia, salivation and decreased body weight and food intake were observed. The solutions were locally well tolerated.

After repeated i.m. injection, the dose of 10 mg/kg was systemically well tolerated, but lesions of muscles at the site of injection were distinctly increased if compared to control rats. At 60 and 120 mg/kg, mortality was high and local damages were dose-dependently increased.

Hyoscine butylbromide was neither embryotoxic nor teratogenic at oral doses of up to 200 mg/kg in the diet (rat) and 200 mg/kg by gavage or 50 mg/kg s.c. (rabbit). Fertility was not impaired at doses of up to 200 mg/kg p.o.

Like other cationic drugs, hyoscine butylbromide interacts with the choline transport system of human placental epithelial cells *in vitro*. Transfer of hyoscine butylbromide to the foetal compartment has not been proved.

Hyoscine butylbromide-suppositories were locally well tolerated.

In special studies concerning local tolerability, a repeated i.m. injection of 15 mg/kg BUSCOPAN<sup>®</sup> over 28 days was studied in dogs and monkeys. Small focal necroses at the site of injection were seen only in dogs. BUSCOPAN<sup>®</sup> was well tolerated in arteries and veins of the rabbit's ear. In vitro, 2 % BUSCOPAN<sup>®</sup> injectable solution showed no haemolytic action when mixed with 0.1 ml human blood.

Hyoscine butylbromide revealed no mutagenic or clastogenic potential in the Ames test, in the in vitro gene mutation assay in mammalian V79 cells (HPRT test) and in an in vitro chromosome aberration test in human peripheral lymphocytes. In vivo, hyoscine butylbromide was negative in the rat bone marrow micronucleus assay.

There are no in vivo carcinogenicity studies. Nevertheless, Hyoscine butylbromide did not show a tumorigenic potential in two oral 26-week-studies in rats given up to 1000 mg/kg.

#### **Availability**

Ampoules 20 mg/ml

**Reg. No. DK12264700143A1**

Box contains 10 ampoules of 1 ml

**Store in < 30°C and protect from light.**

**Store in a safe place out of the reach of children.**

**Only on doctor's prescription.**

**Harus dengan resep dokter.**

**Shelf life: see packaging for expiry date**

#### **Manufactured by:**

SANOFI İLAÇ SAN. VE TIC. A.Ş. Lüleburgaz, Kirklareli, Turkey

#### **For:**

PT Kalventis Sinergi Farma,

Jakarta, Indonesia

#### **Under license from:**

Opella Healthcare International SAS, France

Revision date: 7 October 2025

**Opella.**

## **BUSCOPAN<sup>®</sup> Ampul**

### **Hyoscine-N-butylbromide**

BUSCOPAN<sup>®</sup> Ampul mengandung hyoscine-N-butylbromide (HBB) yang dapat meredakan gejala kram dan nyeri yang datang tiba-tiba dan tidak berlangsung lama pada saluran pencernaan, saluran empedu antara hati dan usus dua belas jari, saluran reproduksi, dan saluran kemih, termasuk nyeri karena batu empedu dan batu ginjal. HBB juga digunakan sebelum pemeriksaan dimana kram dan nyeri menjadi masalah, misalnya pada endoskopi (prosedur minimal invasif yang dilakukan dengan cara memasukkan alat khusus ke dalam saluran pencernaan) dan pada pemeriksaan rontgen, CT scan, MRI, dll.

Sediaan BUSCOPAN <sup>®</sup> Ampul	Kekuatan	Deskripsi Produk
1 ampul @1 ml	20 mg HBB/ampul	BUSCOPAN <sup>®</sup> Ampul dikemas dalam ampul kaca tidak berwarna yang mengandung larutan tidak berwarna atau hampir tidak berwarna, bebas dari partikel yang terlihat

Zat tambahan: *sodium chloride, water for injection.*

#### Dosis dan Cara Pemberian BUSCOPAN<sup>®</sup> Ampul

Usia	Dosis*	Petunjuk Penggunaan
Dewasa dan anak-anak di atas 12 tahun	1-2 ampul (20-40 mg)	<ul style="list-style-type: none"><li>▪ Dapat diberikan melalui suntikan ke pembuluh darah vena secara lambat atau ke jaringan otot beberapa kali sehari</li><li>▪ Jangan gunakan terus menerus dalam jangka panjang tanpa mengetahui penyebab nyeri perut</li></ul>

\*Dosis maksimum per hari tidak boleh melebihi 100 mg.

#### Cara Kerja BUSCOPAN<sup>®</sup> Ampul

BUSCOPAN<sup>®</sup> bekerja spesifik dengan melemaskan otot polos pada saluran pencernaan, saluran empedu, serta saluran reproduksi dan saluran kemih. HBB tidak menembus otak dan sumsum tulang belakang sehingga tidak menyebabkan efek samping yang mengurangi kerja saraf pada otak dan sumsum tulang belakang. Efek BUSCOPAN<sup>®</sup> pada saraf tepi disebabkan oleh penghambatan sel saraf di dinding organ rongga dada dan rongga perut dan penghambatan sinyal saraf tertentu.

Jangan Gunakan BUSCOPAN<sup>®</sup> Ampul jika mengalami glaukoma sudut sempit (kondisi mata yang merusak saraf mata) yang tidak diobati, pembesaran prostat yang membuat susah buang

air kecil, penyempitan pada saluran pencernaan, denyut nadi >100 kali/menit, gangguan pergerakan usus akibat kelumpuhan atau penyumbatan otot usus, pembesaran pada usus besar yang tidak normal, miastenia gravis (gangguan otot dan saraf yang ditandai oleh kelemahan dan kelelahan otot yang berulang), atau alergi terhadap HBB atau bahan lain yang terkandung dalam obat ini.

Perhatikan penggunaan BUSCOPAN® Ampul jika sedang diobati dengan obat pengencer darah karena dapat menyebabkan memar kemerahan di area otot. Pada kondisi ini, pemberian suntikan di bawah kulit atau di pembuluh darah vena dapat digunakan.

Hindari penggunaan BUSCOPAN® Ampul bersamaan dengan obat yang mengurangi kerja saraf tertentu (obat depresi, obat alergi, obat gangguan jiwa, kinidin (obat jantung), amantadine (obat Parkinson), disopiramid (obat gangguan irama jantung), tiotropium, ipratropium (obat sesak napas), atropine (obat pelemas otot)), obat penghambat dopamin, serta adrenergik-beta (obat jantung/tekanan darah).

Penggunaan BUSCOPAN® selama masa kehamilan dan menyusui sebaiknya dihindari.

Tidak ada studi mengenai efek penggunaan BUSCOPAN® terhadap kemampuan mengemudi dan mengoperasikan mesin yang pernah dilakukan.

BUSCOPAN® Ampul dapat mempunyai efek samping yang jarang terjadi seperti reaksi alergi, reaksi kulit seperti ruam, gatal, dan kemerahan, denyut nadi >100 kali/menit, pusing, mengantuk, mulut kering, diare, mual, muntah, nyeri perut, penghambatan sekresi keringat, serta susah buang air kecil.

Pelaporan efek samping

Segera laporkan apabila Anda mengalami keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat kepada [farmakovigilans@kalventis.com](mailto:farmakovigilans@kalventis.com). Anda dapat membantu memberikan informasi terkait keamanan obat ini.

Overdosis penggunaan BUSCOPAN® Ampul dapat menyebabkan susah buang air kecil, mulut kering, kulit kemerahan, denyut nadi >100 kali/menit, serta gangguan penglihatan sementara. Jika mengalami gejala-gejala tersebut, segera berkonsultasi ke dokter. Dokter akan memberikan penanganan sesuai kondisi, termasuk memasang selang kecil ke dalam tubuh (kateter) bila susah buang air kecil.

Kemasan & Cara Penyimpanan BUSCOPAN®

Ampul 20 mg/ml

Reg. No. DKI2264700143A1

Dus berisi 10 ampul @1 ml

Simpan pada suhu <30° C dan terlindung dari cahaya  
Simpan pada tempat yang aman, jauh dari jangkauan anak-anak.

Harus dengan resep dokter

Shelf life: lihat informasi batas kadaluarsa pada kemasan

**Diproduksi oleh:**

Sanofi Ilac San. Ve Tic. A.S. Luleburgaz, Kuklareli, Turkey.

**Untuk:**

PT Kalventis Sinergi Farma

Jakarta, Indonesia

**Dibawah lisensi dari:**

Opella Healthcare International SAS, France

Revision date: 15 December 2025

**Opella.**