Professional Leaflet

Buscopan® Ampoules 20 mg/ml Solution for Injection

(hyoscine butylbromide)

Trade name of the medicinal product

BUSCOPAN Ampoules 20 mg/ml solution for injection.

Qualitative and quantitative composition

Each 1 ml ampoule contains 20 mg hyoscine butylbromide.

For excipients, see List of excipients

Pharmaceutical form

Solution for injection. A colourless or almost colourless, clear solution.

Clinical particulars

Therapeutic indications

BUSCOPAN Ampoules are indicated in acute spasm, as in renal or biliary colic, in radiology for differential diagnosis of obstruction and to reduce spasm and pain in pyelography, and in other diagnostic procedures where spasm may be a problem, e.g. gastroduodenal endoscopy.

Posology and method of administration

Adults: One ampoule (20 mg) intramuscularly or intravenously, repeated after half an hour if necessary.

Intravenous injection should be performed 'slowly', (in rare cases a marked drop in blood pressure and even shock may be produced by BUSCOPAN). When used in endoscopy this dose may need to be repeated more frequently.

Maximum daily dose of 100 mg.

Special populations

Elderly:

No specific information on the use of this product in the elderly is available. Clinical trials have included patients over 65 years and no adverse reactions specific to this age group have been reported.

Paediatric population

Not recommended for children

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

Diluent: BUSCOPAN injection solution may be diluted with dextrose or with sodium chloride 0.9% injection solutions.

Contraindications

Buscopan Ampoules are contraindicated in patients with:

- hypersensitivity to the active substance or to any of the excipients listed in the Pharmaceutical particulars section.

- narrow angle glaucoma

- hypertrophy of the prostate with urinary retention

- mechanical stenosis in the gastrointestinal tract

- paralytical or obstructive ileus

- megacolon

- tachycardia

- myasthenia gravis

BUSCOPAN Ampoules should not be given by intramuscular injection to patients being treated with

anticoagulant drugs since intramuscular haematoma may occur.

Special warnings and precautions for use

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.

BUSCOPAN Ampoules can cause tachycardia, hypotension, and anaphylaxis, therefore use with caution in patients with cardiac conditions, such as cardiac failure, coronary heart disease, cardiac arrhythmia or hypertension, and in cardiac surgery. Monitoring of these patients is advised. Emergency equipment and personnel trained in its use must be readily available.

Because of the possibility that anticholinergics may reduce sweating, BUSCOPAN should be administered with caution to patients with pyrexia.

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.

Interaction with other medicinal products and other forms of interaction

The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antihistamines, quinidine, amantadine, antipsychotics (e.g. phenothiazines, butyrophenones), disopyramide and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by BUSCOPAN. The tachycardic effects of beta-adrenergic agents may be enhanced by BUSCOPAN.

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

Fertility, 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 Pre-clinical safety data). As a precautionary measure 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.

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.

Undesirable effects

Many of the listed undesirable effects can be assigned to the anticholinergic properties of BUSCOPAN.

Adverse events have been ranked under headings of frequency using the following convention:

Very common ≥ 1/10

Common ≥ 1/100, < 1/10

Uncommon ≥ 1/1,000, <1/100

Rare ≥ 1/10,000, <1/1,000

Very rare <1/10,000

Not known cannot be estimated from the

available data

Immune system disorders

Not known*: anaphylactic shock including cases with fatal outcome, anaphylactic reactions, dyspnoea and other hypersensitivity.

Eye disorders

Common: accommodation disorders

Not known*: mydriasis, increased intraocular pressure

Cardiac disorders

Common: tachycardia

Vascular disorders

Common: dizziness

Not known*: blood pressure decreased, flushing

Gastrointestinal disorders

Common: dry mouth

Constipation

Skin and subcutaneous tissue disorders

Not known*: skin reactions (e.g. urticaria, rash, erythema, pruritus), abnormal sweating

Renal and urinary disorders

Not known*: urinary retention

Injection site pain, particularly after intramuscular use, occurs

Hyoscine butylbromide, the active ingredient of BUSCOPAN, due to its chemical structure as a quaternary ammonium derivate, is not expected to enter the central nervous system. Hyoscine butylbromide does not readily pass the blood-brain barrier. However, it cannot totally be ruled out that under certain circumstances psychiatric disorders (e.g. confusion) may also occur after administration of BUSCOPAN.

*This adverse reaction has been observed in post-marketing experience. With 95% certainty, the frequency category is not greater than common, 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 185 patients.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit / risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

HPRA Pharmacovigilance. Website: www.hpra.ie

Overdose

Symptoms: Serious signs of poisoning following acute overdosage have not been observed in man. In the case of overdosage, anticholinergic symptoms 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: 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, artificial respiration should be considered. Catheterisation may be required for urinary retention.

In addition, appropriate supportive measures should be used as required.

Pharmacological properties

Pharmacodynamic properties

BUSCOPAN is an antispasmodic agent which relaxes smooth muscle of the organs of the abdominal and pelvic cavities. It is believed to act predominantly on the intramural parasympathetic ganglia of these organs.

Pharmacokinetic properties

Absorption and distribution

After intravenous administration hyoscine butylbromide is rapidly distributed (t½α = 4 min, t½β = 29 min) into the tissues. The volume of distribution (Vss) 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 (t½γ) 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.

Paediatric population

No particular pharmacokinetic studies concerning hyoscine butylbromide have been performed in children.

Pre-clinical safety data

In limited reproductive toxicity studies hyoscine butylbromide showed no evidence of teratogenicity in rats at 200 mg/kg in the diet or in rabbits at 200 mg/kg by oral gavage or 50 mg/kg by subcutaneous injection.

Fertility in the rat was not impaired at doses up to 200 mg/kg in the diet.

Pharmaceutical particulars

List of excipients:

Sodium chloride

Water for injections

Incompatibilities

None known

Shelf life

Unopened: 36 months

Once opened, use immediately and discard any unused contents.

Special precautions for storage

Store below 30°C

Store in the outer carton in order to protect from light.

Nature and contents of container

1 ml clear glass (Ph. Eur. Type I) ampoules with coloured identification rings, marketed in cartons containing 10 ampoules.

Instructions for use/handling

For single use only. Any unused solution should be discarded.

Marketing Authorisation Holder

Opella Healthcare France SAS

157 avenue Charles de Gaulle

92200 Neuilly-sur-Seine

France.

Marketing Authorisation Number

PA23180/016/001

Manufacturers of the product

Boehringer Ingelheim España, S.A.

Prat de la Riba, 50, 08174 Sant Cugat del Vallès,

Barcelona, Spain

Or

Sanofi S.r.l, Vla Valcanello 4, 03012 Anagni (FR), Italy

Legal Category

POM / S1B

Date of revision of the text

This Professional Leaflet was revised in July 2023.

Malta:
Authorisation n.: AA1470/00202

Package Leaflet: Information for the user

Buscopan® Ampoules

20 mg/ml Solution for Injection

(hyoscine butylbromide)

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT BUSCOPAN AMPOULES ARE AND WHAT THEY ARE USED FOR

The name of your medicine is BUSCOPAN Ampoules 20 mg/ml Solution for injection (called BUSCOPAN Ampoules in this leaflet). BUSCOPAN Ampoules contain a medicine called 'hyoscine butylbromide'. This belongs to a group of medicines called 'antispasmodics'. BUSCOPAN Ampoules are used to relieve cramps in the muscles of your:

- Stomach
- Gut (intestine)
- Bladder and the tubes leading to the outside of your body (urinary system)

BUSCOPAN Ampoules can also be used in some diagnostic and therapeutic medical procedures where spasm may be a problem for example barium enema.

2. BEFORE YOU RECEIVE BUSCOPAN AMPOULES

You should not be given BUSCOPAN Ampoules if:

- You are allergic (hypersensitive) to hyoscine butylbromide or any of the other ingredients (listed in Section 6)
- You have glaucoma (an eye problem)
- You have megacolon (a very enlarged bowel)
- You have something called 'myasthenia gravis' (a very rare muscle weakness problem)
- You have a very fast heart rate
- You have difficulty or pain passing water (urine) such as men with prostate problems
- You have gut blockage problems or a totally inactive gut
- You are pregnant, likely to get pregnant or are breast-feeding

You should not receive this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Take special care with BUSCOPAN Ampoules

Check with your doctor or pharmacist before having this medicine if:

- You have any heart problems
- You have a fever
- You have problems with your thyroid gland such as an overactive thyroid gland

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before receiving BUSCOPAN Ampoules.

Check with your doctor or pharmacist straight away if you have unexplained abdominal pain which persists or worsens or occurs with:

- fever
- feeling sick
- being sick
- changes in your bowel movements
- abdominal tenderness
- low blood pressure
- feeling faint or,
- blood in your bowel movements

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because BUSCOPAN Ampoules can affect the way some other medicines work. Also some other medicines can affect the way BUSCOPAN Ampoules work.

In particular tell your doctor or pharmacist if you are taking any of the following:

- Medicines for depression called 'tetracyclic antidepressants' or 'tricyclic antidepressants' such as doxepin
- Medicines for allergies and travel sickness called 'antihistamines'
- Medicines to control your heart beat such as quinidine or disopyramide
- Medicines for severe mental illness such as haloperidol or fluphenazine
- Medicines usually used for breathing problems such as salbutamol, ipratropium, tiotropium or atropine-like medicines
- Amantadine - for Parkinson's disease and flu
- Metoclopramide - for feeling sick (nausea)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before receiving BUSCOPAN Ampoules.

Pregnancy and breast-feeding

You should not be given BUSCOPAN Ampoules if you are pregnant, likely to get pregnant or are breast-feeding.

Driving and using machines

Some people may have sight problems or feel dizzy while taking this medicine. If this happens to you, wait until your sight returns to normal or you stop feeling dizzy before driving or using any tools or machines.

Important information about some of the ingredients of BUSCOPAN Ampoules

BUSCOPAN Ampoules contain sodium chloride. The amount of sodium in a 1 ml ampoule is less than 1 mmol (23 mg), the total amount of sodium if you are given five ampoules in 24 hours is less than 1 mmol (23 mg) this means that your medicine is essentially sodium free.

3. HOW BUSCOPAN AMPOULES WILL BE GIVEN

BUSCOPAN Ampoules are usually given by a doctor or nurse. BUSCOPAN Ampoules should not be given every day for long periods of time.

Receiving the injection

BUSCOPAN Ampoules may be given in two ways:

- By being slowly injected into a vein
- By an injection into a muscle
- BUSCOPAN Ampoules may be diluted with other solutions if needed

How much will you be given

- You will usually be given one ampoule, but you may be given a further ampoule after half an hour if required
- If you are being given BUSCOPAN Ampoules as part of an endoscopy your dose may need to be given more often
- You should not be given more than 5 ampoules in any 24-hour period

BUSCOPAN Ampoules are not recommended for children.

If you have more BUSCOPAN Ampoules than you should

It is unlikely that you will be given too much of this medicine. However, tell the doctor or nurse if you think that you have been given too much.

4. POSSIBLE SIDE EFFECTS

Like all medicines, BUSCOPAN Ampoules can cause side effects although not everybody gets them. The following side effects may happen with this medicine.

Stop taking your medicine and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

- Allergic reactions such as skin rash, nettle rash, redness of the skin and itching
- Severe allergic reactions (anaphylaxis) such as difficulty breathing, feeling faint or dizzy (shock)
- Painful red eye with loss of vision

Other side effects

- Dry mouth (affects fewer than 1 in 10 people)
- Dizziness (affects fewer than 1 in 10 people)
- Blurred vision (affects fewer than 1 in 10 people)
- Increased heart rate (affects fewer than 1 in 10 people)
- Constipation
- Abnormal sweating or reduced sweating

- Being unable to pass water (urine)
- Low blood pressure, for example feeling faint
- Flushing
- Dilated pupils
- Increased fluid pressure inside the eye

Pain at the place you had the injection may occur if you have been given BUSCOPAN Ampoules into a muscle.

Although unlikely, in certain circumstances it may be possible that BUSCOPAN may pass into the brain and cause side effects, for example confusion.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BUSCOPAN AMPOULES

- Keep out of the reach and sight of children
- Store below 30°C, keep the ampoules in the outer carton in order to protect from light
- BUSCOPAN Ampoules should not be used after the expiry date which is printed on the carton and ampoules. The expiry date refers to the last day of that month

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What BUSCOPAN Ampoules contain

Each ampoule contains 20 mg of the active ingredient hyoscine butylbromide. The other ingredients are sodium chloride and water for injections.

What BUSCOPAN Ampoules looks like and contents of the pack

BUSCOPAN Ampoules are clear glass ampoules with coloured identification rings, containing a colourless or almost colourless, clear solution.

BUSCOPAN Ampoules are supplied in cartons containing 10 x 1 ml ampoules.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation is held by:

Opella Healthcare France SAS

157 avenue Charles de Gaulle

92200 Neuilly-sur-Seine

France.

Manufacturer:

Boehringer Ingelheim España, S.A.

Prat de la Riba, 50 08174 Sant Cugat del Vallès,

Barcelona, Spain

Or

Sanofi S.r.l

Vla Valcanello 4,

03012 Anagni (FR),

Italy

For any information about this medicine, please contact the distributor & local representative of the Marketing Authorisation Holder:

Clonmel Healthcare Ltd.,

Waterford Road, Clonmel,

Co. Tipperary, Ireland.

Tel: +353 52 617 7777

Email: medicalinformation@clonmel-health.ie

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