Buscopan® Ampoules

for Injection

(For use in duodenal ulceration)

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 exceptions, 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. gastrointestinal 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.

Contraindications
Buscopan® Ampoules are contraindicated in patients with:
- myasthenia gravis
- tachycardia
- megacolon
- paralytical or obstructive ileus
- mechanical stenosis in the gastrointestinal tract
- hypertrophy of the prostate with urinary retention

Other contraindications
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
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.

The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antihistamines, spasmolytics, antipsychotics (e.g. phenothiazines, butyrophenones), antiparkinsonian agents (e.g. trihexyphenidyl, levodopa, dopamine receptor blockers), sympathomimetic amine-like compounds may be intensified by BUSCOPAN. The anticholinergic effects of beta-adrenergic agents may be enhanced by BUSCOPAN.

Interaction with other medicinal products and other forms of interaction
No studies have been performed. However, patients should be advised that they may experience undesirable effects such as accommodation disorder or diarrhoea during treatment with BUSCOPAN Ampoules.

Buscopan® Ampoules are not recommended for continuous daily or for extended periods without investigating the cause of abdominal pain.

Effects on ability to drive and use machines
No studies have been performed. However, patients should be advised that they may experience undesirable effects such as accommodation disorder or diarrhoea during treatment with BUSCOPAN Ampoules.

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 diarrhoea during treatment with BUSCOPAN Ampoules.

Adverse reactions
Adverse reactions have been ranked under headings of frequency using the following convention:
Not reported
<1/10,000
≥ 1/10,000, <1/1,000
≥ 1/1,000, <1/100
≥ 1/100, <1/10
≥ 1/10

Effects on general physical and mental abilities
Adverse reactions noted during routine clinical evaluation of BUSCOPAN Ampoules solution are:

- dry mouth
- dilated pupils
- tachycardia
- pyrexia
- constipation
- sweating

Undesirable effects
Adverse reactions have been ranked under headings of frequency using the following convention:
Very common
1/1,000, >1/100
Common
<1/100, ≥1/1,000
Uncommon
<1/10,000, ≥1/1,000
Rare
<1/100,000
Not known
cannot be estimated from the available data.

Effects on the blood
Adverse reactions noted during routine clinical evaluation of BUSCOPAN Ampoules solution are:

- dry mouth
- dilated pupils
- tachycardia
- pyrexia
- constipation
- sweating

Fertility, pregnancy and lactation
Pregnancy
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 diarrhoea during treatment with BUSCOPAN Ampoules.

Adverse reactions noted during routine clinical evaluation of BUSCOPAN Ampoules solution are:

- dry mouth
- dilated pupils
- tachycardia
- pyrexia
- constipation
- sweating

Hypersensitivity Reactions
Some 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
1/1,000, >1/100
Common
<1/100, ≥1/1,000
Uncommon
<1/10,000, ≥1/1,000
Rare
<1/100,000
Not known
cannot be estimated from the available data.

Effects on the blood
Adverse reactions noted during routine clinical evaluation of BUSCOPAN Ampoules solution are:

- dry mouth
- dilated pupils
- tachycardia
- pyrexia
- constipation
- sweating

Adverse reactions noted during routine clinical evaluation of BUSCOPAN Ampoules solution are:

- dry mouth
- dilated pupils
- tachycardia
- pyrexia
- constipation
- sweating

Blood pressure
- hypertension
- hypotension
- fainting
- blood in stool

Blood
- changes in bowel movements, abdominal tenderness, decreased blood pressure, fainting, or blood in stool

Fertility
- no adverse reactions specific to this age group have been reported.

Effects on the heart
- no adverse reactions specific to this age group have been reported.

Effects on the respiratory system
- no adverse reactions specific to this age group have been reported.

Effects on the central nervous system
- no adverse reactions specific to this age group have been reported.

Effects on the gastrointestinal tract
- no adverse reactions specific to this age group have been reported.

Effects on the genitourinary system
- no adverse reactions specific to this age group have been reported.

Effects on the skin
- no adverse reactions specific to this age group have been reported.

Medication of choice
No studies have been performed. However, patients should be advised that they may experience undesirable effects such as accommodation disorder or diarrhoea during treatment with BUSCOPAN Ampoules.

Adverse reactions noted during routine clinical evaluation of BUSCOPAN Ampoules solution are:

- dry mouth
- dilated pupils
- tachycardia
- pyrexia
- constipation
- sweating

Adverse reactions noted during routine clinical evaluation of BUSCOPAN Ampoules solution are:

- dry mouth
- dilated pupils
- tachycardia
- pyrexia
- constipation
- sweating

Fertility
- no adverse reactions specific to this age group have been reported.

Effects on the skin
- no adverse reactions specific to this age group have been reported.

Effects on the nervous system
- no adverse reactions specific to this age group have been reported.

Effects on the respiratory system
- no adverse reactions specific to this age group have been reported.

Effects on the gastrointestinal tract
- no adverse reactions specific to this age group have been reported.

Effects on the genitourinary system
- no adverse reactions specific to this age group have been reported.

Effects on the skin
- no adverse reactions specific to this age group have been reported.

Medication of choice
No studies have been performed. However, patients should be advised that they may experience undesirable effects such as accommodation disorder or diarrhoea during treatment with BUSCOPAN Ampoules.

Adverse reactions noted during routine clinical evaluation of BUSCOPAN Ampoules solution are:

- dry mouth
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- constipation
- sweating

Adverse reactions noted during routine clinical evaluation of BUSCOPAN Ampoules solution are:

- dry mouth
- dilated pupils
- tachycardia
- pyrexia
- constipation
- sweating

Fertility
- no adverse reactions specific to this age group have been reported.

Effects on the skin
- no adverse reactions specific to this age group have been reported.

Effects on the nervous system
- no adverse reactions specific to this age group have been reported.

Effects on the respiratory system
- no adverse reactions specific to this age group have been reported.

Effects on the gastrointestinal tract
- no adverse reactions specific to this age group have been reported.

Effects on the genitourinary system
- no adverse reactions specific to this age group have been reported.

Effects on the skin
- no adverse reactions specific to this age group have been reported.

Medication of choice
No studies have been performed. However, patients should be advised that they may experience undesirable effects such as accommodation disorder or diarrhoea during treatment with BUSCOPAN Ampoules.
BUCONAL is an antispasmodic agent which relaxes smooth muscle of the organs of the abdominal and pelvic cavities. It is believed to act primarily on the intramural parasympathetic plexus of these organs.

Pharmacodynamic properties

Intravenous administration of hyoscine butylbromide is rapidly distributed (1/4 to 1 hour). It is not metabolised in the liver, but undergoes a minor degree of metabolism in the plasma. Plasma protein binding (albumin) of hyoscine butylbromide is approximately 44%. Animal studies demonstrate that hyoscine butylbromide does not pass the blood-brain barrier.

Absorption and distribution

After intravenous administration, hyoscine butylbromide showed no evidence of bioavailability in rats at 200 mg/kg or in the diet or in rabbits at 200 mg/kg by oral gavage or 50 mg/kg by subcutaneous injection. Fertility in the males was not impaired as shown up to 200 mg/kg in the diet.

Pharmacokinetic properties

Hyoscine butylbromide is mainly distributed in the extracellular space. Plasma protein binding (albumin) of hyoscine butylbromide is approximately 44%. 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 mg/kg) has been observed to interact with the cholinergic transport (0.4 mg) in autonomic cells of human placenta in vitro.

Adverse reactions

The main metabolic pathway is the hydrolytic cleavage of the ester bond. This hydrolysis of the terminal ester phase (1% of hyoscine) is approximately 9 hours. The terminal clearance is 1.2 L/min. Clinical studies with radiolabelled hyoscine butylbromide showed that after intravenous injection 62 to 67% of the radiolabeller dose is excreted renally and 28.3 to 31.7% faecally. The portion of unchanged active ingredient excreted in the urine is approximately 50%.

The metabolism occurs in the renal cortex and partially enters the mesenchymal cells and is therefore considered to contribute to the effect of the hyoscine butylbromide.

Investigations

In particular preclinical studies concerning hyoscine butylbromide have been performed in children.

Preclinical 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 males was not impaired as shown up to 200 mg/kg in the diet.

Pharmacological particular

List of excipients

Sodium chloride

Water for injections

Incompatibilities

None known

Shelf-life

Unopened, 5 years

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 marketed in cartons containing 1 to 5 ampoules.

Manufacturing Authorisation Number

PA 540/181/1

PL 04425/0707

Citywest Business Campus, Dublin 24, Ireland

Marketing Authorisation Holder

United Kingdom

Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, United Kingdom

Marketing Authorisation Number

PL 04425/0707

PA 540/181/1

Manufacturing of the product

Sanofi, Pris de la Riba, 50, 08174 Sant Cugat del Vallès, Barcelona, Spain

Legal Category

POM / S1B

Date of revision of the text

22/03/2017

This Professional Leaflet was reviewed in October 2017.

Emergency system disorders

Not known*: epileptic shock including cases with fatal outcome, anaphylactic reactions, dyspnoea, skin reactions (e.g. urtica, rash, erythema, pruritus) and other hypersensitivity.

Eye disorders

Not known*: epiphora, dry eyes.

Cardiac disorders

Not known*: atrial tachycardia.

Vascular disorders

Not known*: hypertension.

Renal and urinary disorders

Not known*: urinary retention.

Respiratory disorders

Injection site pain, particularly after intramuscular use, occurs occasionally.

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 usually be ruled out that rather certain adverse effects on the central nervous system (e.g. hallucinations) may also occur after administration of BUSCOPAN.

This adverse reaction has been observed in post-marketing experience: With 3% certainty, the frequency category is not greater than common, but might be lower. Hyoscine butylbromide is not considered to contribute to the effect of the hyoscine butylbromide.

Gastrointestinal disorders

Common: dizziness.

Vascular disorders

Not known*: mydriasis, increased intraocular pressure.

Eye disorders

Common: accommodation disorders.

Skin and subcutaneous tissue disorders

Not known*: dyshidrosis.

Common: dry mouth.

Renal and urinary disorders

Not known*: urinary retention.

Cardiac disorders

Not known*: atrial tachycardia.

Gastrointestinal disorders

Common: dizziness.

Vascular disorders

Not known*: mydriasis, increased intraocular pressure.

Eye disorders

Common: accommodation disorders.

Skin and subcutaneous tissue disorders

Not known*: dyshidrosis.

Common: dry mouth.

Renal and urinary disorders

Not known*: urinary retention.

Cardiac disorders

Not known*: atrial tachycardia.

Gastrointestinal disorders

Common: dizziness.
Buscapan® 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
2. Before you receive BUSCOPAN Ampoules
3. How BUSCOPAN Ampoules will be given
4. Possible side effects
5. How to store BUSCOPAN Ampoules
6. Further Information

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 myasthenia (a very rare muscle weakness problem)
• You have something called ‘myasthenia gravis’
• You have symptoms are the same as yours.
• You have megacolon (a very enlarged bowel)
• You have glaucoma (an eye problem)
• You have anything called ‘tetracyclic antidepressants’ such as doxepin
• You have Parkinson’s disease and flu
• You have a fever
• You have any heart problems
• 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 occur with:
• Fever
• Feeling sick
• Changes in your bowel movements
• Abdominal tenderness
• Low blood pressure
• Feeling faint or
• Irregular 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 or have recently taken 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, theophylline or atropine-like medicines
• Amantadine - for Parkinson’s disease and flu
• Meclozine - for feeling sick (nausea)
• Amantadine - for Parkinson’s disease and flu
• 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
• Small blisters on hands and feet
• 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 (see details below).

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 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 Authorisations are held by:

United Kingdom
Sanofi, One Osmo Drive, Guildford, Surrey, GU4 4YS, United Kingdom.
Tel: 0845 372 7102
Email: uk_medicalinformation@sanofi.com

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and the ampoules are manufactured at:
Boehringer Ingelheim España, S.A.
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