Buscapan® Ampoules
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.

Dosage and administration

Intramuscular injection
Adults: One ampoule (20 mg) intramuscularly or intravenously, followed after half an hour or if necessary. Intravenous injection should be performed slowly. For rare cases of marked drop in blood pressure and near shock may be produced by BUSCOPAN. When used in elderly this dose may need to be repeated more frequently.

Maximum daily dose of 150 mg.

Paediatric population
Not recommended for children

Contraindications

- Prior hypersensitivity to hyoscine butylbromide or any other component of the product.
- Myasthenia gravis.
- Narrow angle glaucoma.
- Myocardial infarction.
- Severe cardiac arrhythmia or hypertension, and in cardiac surgery.
- Monitoring of anaphylaxis, therefore use with caution in patients with cardiac arrhythmia or hypertension.

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

Very common ≥ 1/10
Common ≥ 1/100, <1/10
Rare ≥ 1/10,000, <1/100
Very rare <1/100,000

The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antipsychotics (e.g. phenothiazines, butyrophenones), antispasmodics (e.g. neostigmine), antihistamines, decongestants, and spasmolytics (e.g. metoclopramide) may result in diminution of the effects of both drugs on the gastrointestinal tract.

Effects on ability to drive and use machines

No studies on the effects on human fertility have been conducted. No studies on the effects of injection solution 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.

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

No studies on the effects on human fertility have been conducted. There are limited data from the use of hyoscine butylbromide in pregnant women. Animal studies have shown that treatment with anticholinergic agents may result in teratogenicity in the offspring of pregnant rabbits. As a precautionary measure BUSCOPAN is not recommended during pregnancy.

Breastfeeding
Breastfeeding is not recommended. Breastfeeding child cannot be excluded. Use of BUSCOPAN during breastfeeding is not recommended if the mother continues to use the product.

Undesirable effects

- Because of the possibility that anticholinergics may reduce sweating, BUSCOPAN should be administered with caution in patients with pyrexia.
- Elevation of intracranial pressure may be produced by the administration of anticholinergic agents such as BUSCOPAN to patients with and pre-existing and therefore untreated narrow angle glaucoma. Therefore, patients should seek urgent ophthalmological advice in case they develop a painful, red eye with loss of vision after the injection of BUSCOPAN.
- After parental 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

- BUSCOPAN Ampoules should not be given by intramuscular injection to patients being treated with anticoagulant drugs since intramuscular haematoma may occur.
- BUSCOPAN injection solution may be diluted with dextrose or with sodium chloride 0.9% injection solutions.
- Hyperactive bowel movements, abdominal distension, nausea and vomiting, are rare cases and may be treated with antispasmodics, which can control symptoms. Broadening of the duodenal endoscopy.

Effects of interaction

- Concomitant treatment with dopamine antagonists such as metoclopramide may result in diminution of the effects of both drugs on the gastrointestinal tract.
- The anticholinergic effect of drugs such as tricyclic antidepressants, antipsychotics, antihistamines, decongestants, and spasmolytics (e.g. neostigmine) may result in diminution of the effects of both drugs on the gastrointestinal tract.
- BUSCOPAN by injection should be kept under observation.
- 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.
- After parental 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.

Fertility, pregnancy and lactation

No studies on the effects on human fertility have been conducted. No studies on the effects of injection solution 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.

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immune system disorders
Not known*: urinary retention

Renal and urinary disorders
Common: dry mouth

Gastrointestinal disorders
Not known*: blood pressure decreased, flushing

Cardiovascular disorders
Common: dry mouth

Central nervous system disorders
Not known*: blood pressure decreased

Psychiatric disorders
Common: tachycardia

Eye disorders
Not known*: mydriasis, increased intraocular pressure

Ears and sense organ disorders
Common: accommodation disorders

Skin and subcutaneous tissue disorders
Not known*: nausea

Musculoskeletal disorders
Not known*: myalgia

Other adverse reactions
Common: flushing, red face, dizziness, dry mouth

Overdose
Under normal dosage no evidence of overdosage has been noted. In the event of accidental overdosage, symptoms such as tachycardia and flushing may occur, and Cheynes-Stokes respiration has been reported. Patients should be treated according to usual therapeutic principles. In case of severe overdosage, anticholinergic symptoms such as urinary retention, cardiovascular complications, and severe respiratory paralysis may be observed. In this case, intubation and artificial respiration with positive pressure are required. Vomiting and diaphoresis may occur after administration of BUSCOPAN.

Contraindications
The contraindications are as follows:

- Pregnancy
- Breastfeeding
- Newborns and premature infants
- Children aged <3 years
- Patients with glaucoma
- Patients with acute angle-closure glaucoma
- Patients with obstructive uropathy
- Patients with pyloric stenosis
- Patients with iridocorneal angle obstruction
- Patients with urinary tract obstruction
- Patients with undiagnosed abdominal pain

Precautions for use

- As with any anticholinergic, BUSCOPAN should not be used in patients with reduced cardiac output or in those with a history of cardiac disease.
- BUSCOPAN should not be used in patients with obstructive uropathy, pyloric stenosis, iridocorneal angle obstruction, urinary tract obstruction, undiagnosed abdominal pain, or patients with a history of cardiac disease.
- BUSCOPAN should not be used in patients with iridocorneal angle obstruction, as it may cause an increase in intraocular pressure.
- BUSCOPAN should not be used in patients with undiagnosed abdominal pain, as it may cause an increase in intraocular pressure.

Special precautions for handling

- BUSCOPAN should be handled with care to avoid skin contact.
- BUSCOPAN should be stored in a cool, dry place, away from direct sunlight.

Special precautions for storage

- BUSCOPAN should be stored in a cool, dry place, away from direct sunlight.

Instructions for use/handling

- BUSCOPAN should be used according to the instructions provided in the package insert.

Marketing Authorisation Holder

Boehringer Ingelheim España, S.A.
Prat de la Riba, 50, 08174 Sant Cugat del Vallès, Barcelona, Spain

Marketing Authorisation Number

PL 00015/5005R
PA 7/16/2

Manufacture of the product

Boehringer Ingelheim España, S.A.
Prat de la Riba, 50, 08174 Sant Cugat del Vallès, Barcelona, Spain

Legal Category

POM / S1B

Date of revision of the text

This Professional Leaflet was revised in November 2016.

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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
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 there 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'
• You have glaucoma (an eye problem)
• You have a very fast heart rate
• You have difficulty or pain passing water (urine)
• You have something called 'malabsorption'
• You have problems with your thyroid gland such as an overactive thyroid gland

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,
• Mottled 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 'tricyclic antidepressants' or 'tetracyclic antidepressants' such as doxepin
• Medicines for allergies and travel sickness called 'antihistamines'
• Medicines to control your heart beat such as quinidine or disopyramide
• Medicines to control your heart beat such as quinidine or disopyramide
• Medicines for severe mental illness such as haloperidol or trifluoperazine
• Medicines usually used for breathing problems such as salbutamol, ipratropium, terbutaline 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 side effects 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.
- 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 have, 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). 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 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:
Boehringer Ingelheim Limited, Eiselefield Avenue, Bracknell, Berkshire, RG12 8YJ, United Kingdom
and the ampoules are manufactured at:
Boehringer Ingelheim España, S.A.\nPrat de la Ribó, 50\n08174 Sant Cugat del Vallés, Barcelona, Spain

This leaflet was revised in June 2014. © Boehringer Ingelheim Limited 2014