Approved Professional Information for BUSCOPAN® 0,1 % syrup

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

BUSCOPAN® 0,1 % syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL of syrup contains 5 mg of hyoscine butylbromide.

Preservative: Sorbic acid 0,080 % *w/v*.

Sugar free.

Contains sweetener. Each 5 mL of syrup contains 15 mg of saccharin sodium.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

A clear colourless to slightly yellow viscous liquid with a banana odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BUSCOPAN is used in the treatment of conditions associated with gastrointestinal spasm.

4.2. Posology and method of administration

Posology

Babies older than 1 month up to 3 months: 2,5 mL three times daily

Infants older than 3 months up to 1 year: 2,5 mL – 5 mL three times daily

Children older than 1 year up to 3 years: 5 mL – 10 mL three times daily

Children older than 3 years up to 6 years: 10 mL three times daily

Children older than 6 years up to 12 years: 10 mL – 20 mL three times daily

Children older than 12 years and adults: 20 mL four times daily

The initial dose must be the lowest recommended for age.

Do not exceed the maximum recommended dose for age.

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

4.3 Contraindications

BUSCOPAN is contraindicated in:

- patients who have demonstrated prior hypersensitivity to hyoscine butylbromide or any other component of the product (see section 6.1)
- myasthenia gravis
- mechanical stenosis in the gastrointestinal tract
- paralytic or obstructive ileus
- megacolon
- narrow angle glaucoma
- porphyria
- enlarged prostate
- fever
- tachycardia.

4.4 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, medical advice should immediately be sought.

Because of the potential risk of anticholinergic complications, caution should be used in patients prone to narrow angle glaucoma as well as in patients susceptible to intestinal or urinary outlet obstructions and in those inclined to tachyarrhythmia.

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 medicines 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 whilst or after taking Buscopan.

Caution is advised in patients with impaired metabolic, liver or kidney function, as adverse central nervous system effects may be more likely in these patients.

Cases of anaphylaxis including episodes of shock have been observed.

4.5 Interaction with other medicines and other forms of interaction

The anticholinergic effect of medicines such as tri- and tetracyclic antidepressants, antihistamines, quinidine, amantadine, antipsychotics (e.g. butyrophenones, phenothiazines), 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 medicines on the gastrointestinal tract.

The tachycardic effects of beta-adrenergic medicines may be enhanced by BUSCOPAN.

BUSCOPAN should be used with caution in patients receiving other central depressants concomitantly as central nervous system depression may be enhanced.

4.6 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. As a precautionary measure BUSCOPAN is not recommended during pregnancy.

Breastfeeding

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.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. Because of possible visual accommodation disturbances patients should not drive or operate machinery if affected.

4.8 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 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000); not known (cannot be estimated from the available data).

Immune system disorders

Not known*: anaphylactic shock, anaphylactic reactions, dyspnoea, other hypersensitivity

Cardiac disorders

Uncommon: tachycardia

Not known: bradycardia followed by tachycardia with palpitations and arrhythmias

Gastrointestinal disorders

Uncommon: dry mouth

Skin and subcutaneous tissue disorders

Uncommon: skin reactions (e.g. urticaria, pruritus), abnormal sweating

Not known*: rash, erythema

Renal and urinary disorders

Rare: urinary retention.

* This adverse reaction has been observed in post-marketing experience. With 95 % certainty, the frequency category is not greater than uncommon (3/1 368), 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 1 368 patients.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of BUSCOPAN is important. It allows continued monitoring of the benefit/risk balance of BUSCOPAN. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

- https://www.sahpra.org.za/Publications/Index/8, or to the
- Pharmacovigilance Unit at Sanofi at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

4.9 Overdose

Symptoms

In case of overdose, anticholinergic effects may be observed.

Toxic doses cause tachycardia, rapid or stertorous respiration, hyperpyrexia, restlessness, confusion and excitement, and hallucinations passing into delirium. A rash may appear on the face and upper trunk. In severe intoxication depression of the central nervous system may occur with hypertension or circulatory failure and respiratory depression. Quaternary ammonium anticholinergic medicines such as BUSCOPAN usually have some ganglion-blocking activity so that high doses may cause postural hypotension; in toxic doses non-depolarising neuro-muscular block may be produced.

Therapy

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hyoscine butylbromide belongs to the medicine class A 11.2 Gastro-intestinal antispasmodics and cholinolytics (anticholinergics).

Hyoscine butylbromide is a quaternary ammonium anticholinergic medicine that acts at the parasympathetic ganglia in the walls of the viscera where it exerts a specific antispasmodic action on the smooth muscle of the gastrointestinal, biliary and urinary tracts.
As a quaternary ammonium derivative, hyoscine butylbromide does not readily pass the blood-brain barrier to enter the central nervous system.

5.2 Pharmacokinetic properties

Absorption

As a quaternary ammonium compound, hyoscine butylbromide is highly polar and hence only partially absorbed following oral (8 %) or rectal (3 %) administration. After oral administration of single doses of hyoscine butylbromide in the range of 20 to 400 mg, mean peak plasma concentrations between 0,11 ng/mL and 2,04 ng/mL were found at approximately 2 hours. In the same dose range, the observed mean $AUC_{0\text{-}tz}$-values varied from 0,37 to 10,7 ng h/mL. The median absolute bioavailabilities of different dosage forms, i.e. coated tablets, suppositories and oral solution, containing 100 mg of hyoscine butylbromide each were found to be less than 1 %.

Distribution

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

Following oral administration of single doses in the range of 100 to 400 mg, the terminal elimination half-lives ranged from 6,2 to 10,6 hours. The main metabolic pathway is the hydrolytic cleavage of the ester bond. Orally administered hyoscine butylbromide is excreted in the faeces and in the urine. Studies in man show that 2 to 5 % of radioactive doses is eliminated renally after oral, and 0,7 to 1,6 % after rectal administration. Approximately 90 % of recovered radioactivity can be found in the faeces after oral administration. The urinary excretion of hyoscine butylbromide is less than 0,1 % of the dose. The mean apparent oral clearances after oral doses of 100 to 400 mg range from 881 to 1420 L/min, whereas the corresponding volumes of distribution for the same range vary from 6,13 to 11,3 x 10^5 L, probably due to very low systemic availability. 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium

Hydroxyethylcellulose

Banana flavour

Water purified.

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light.

6.5 Nature and contents of container

Amber glass bottle of 100 mL with a white polypropylene tamper-evident closure with an expanded polyethylene liner.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Opella Healthcare South Africa (Pty) Ltd

4th Floor, Building I, Hertford Office Park, 90 Bekker Road,

Midrand, 1652

8. REGISTRATION NUMBER

Z/11.2/93

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 March 1993

10. DATE OF REVISION OF THE TEXT

13 April 2022

NAMIBIA Reg. No.: 04/11.2/1607	NS1

Approved Patient Information Leaflet for BUSCOPAN 0,1 % syrup

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

BUSCOPAN® 0,1 % syrup

Hyoscine butylbromide

Sugar free.

Contains sweetener.

Contains 15 mg of saccharin sodium per 5 mL.

Read all of this leaflet carefully because it contains important information for you.

BUSCOPAN 0,1 % syrup is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use BUSCOPAN 0,1 % syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What BUSCOPAN 0,1 % syrup is and what it is used for

Hyoscine butylbromide belongs to a group of medicines called antispasmodics (medicines that relax the cramping muscles of your stomach and bowel).

BUSCOPAN 0,1 % syrup is used in the treatment of conditions associated with gastrointestinal spasm, that is, to relieve cramps in the muscles of the stomach and gut.

2. What you need to know before you take BUSCOPAN 0,1 % syrup

Do not take BUSCOPAN 0,1 % syrup

- if you are hypersensitive (allergic) to hyoscine butylbromide or any of the other ingredients (listed in section 6)
- if you have myasthenia gravis (a very rare muscle weakness problem)
- if you have suspected or confirmed blockage of the bowel
- if you have a condition where the bowel is blocked and does not work properly (paralytic or obstructive ileus)
- if you have a very enlarged bowel (megacolon)
- If you have glaucoma (an eye problem with increased pressure in the eye)

- if you have porphyria (disturbances of metabolism that can be seen as disorders of the skin or other organs)
- if you have an enlarged prostate
- if you have a fever
- if you have tachycardia (fast heartbeat).

Warnings and precautions

Take special care with BUSCOPAN 0,1 % syrup:

Consult your doctor, pharmacist or other health care provider straight away:

If you have severe, unexplained abdominal (belly) pain that persists or worsens or occurs together with fever, nausea (feeling sick), vomiting, changes in your bowel movements, abdominal (belly) tenderness, low blood pressure, fainting or blood in your bowel movements.

Consult your doctor, pharmacist or other health care provider before taking BUSCOPAN 0,1 % syrup:

- if you tend to have a very fast heart rate or other heart problems
- if you have a tendency to blockage problems of the gut or urinary tract or if you have difficulty or pain passing water (urine) such as men with prostate problems
- if you are prone to glaucoma (increased pressure in the eye)
- if you have been treated by a doctor for a severe sweating problem
- if you have a fever
- if you have abnormal liver or kidney function.

Other medicines and BUSCOPAN 0,1 % syrup

Always tell your health care provider if you are taking any other medicine. (This includes all

complementary or traditional medicines.)

BUSCOPAN 0,1 % syrup can interfere with some other medicines, in particular:

- Antihistamines – used to treat hayfever and other allergies.
- Tricyclic or tetracyclic antidepressant medicines – used to treat depression.
- Quinidine or disopyramide – used to control your heartbeat.
- Amantadine – used for Parkinson's disease and flu.
- Antipsychotic medicines such as butyrophenones or phenothiazines – used to treat severe mental illness such as schizophrenia.
- Tiotropium, ipratropium or atropine-like medicines – medicines inhaled to treat breathing problems.
- Dopamine antagonists such as metoclopramide for feeling nauseous.
- Beta-adrenergic medicines such as salbutamol for asthma.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not use BUSCOPAN if you are pregnant or breastfeeding your baby.

Driving and using machines

Some people may have temporary blurring of vision while taking BUSCOPAN 0,1 % syrup. If this happens to you, wait until your vision returns to normal before driving or using any tools or machines.

3. How to take BUSCOPAN 0,1 % syrup

Always take BUSCOPAN 0,1 % syrup exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Babies older than 1 month up to 3 months: 2,5 mL (half a medicine measure) three times daily.

Infants older than 3 months up to 1 year: 2,5 mL – 5 mL (half to 1 medicine measure) three times daily.

Children older than 1 year up to 3 years: 5 mL – 10 mL (1 to 2 medicine measures) three times daily.

Children older than 3 years up to 6 years: 10 mL (2 medicine measures) three times daily.

Children older than 6 years up to 12 years: 10 mL – 20 mL (2 to 4 medicine measures) three times daily.

Children older than 12 years and adults: 20 mL (4 medicine measures) four times daily.

The first dose must be the lowest recommended for age.

Do not take more than the maximum recommended dose for age.

BUSCOPAN 0,1 % syrup should not be taken on a continuous daily basis or for long periods without investigating the cause of the pain. You must see a doctor if your symptoms worsen or do not improve after 3 days.

If you take more BUSCOPAN 0,1 % syrup than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BUSCOPAN 0,1 % syrup

If you miss a dose, take it as soon as you remember. If it is nearly time for your next dose, skip the missed dose and go back to your usual dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BUSCOPAN 0,1 % syrup may have side effects.

Not all side effects reported for BUSCOPAN 0,1 % syrup are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BUSCOPAN 0,1 % syrup, please consult your health care provider for advice.

If any of the following happens, stop taking BUSCOPAN 0,1 % syrup and tell your doctor immediately or go to the casualty department at your nearest hospital. You may need urgent medical attention:

- Anaphylactic reaction and shock – this is a severe type of allergic reaction. The itchy rash may spread all over the body, as well as swelling. You may have difficulty in breathing and may lose consciousness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BUSCOPAN 0,1 % syrup. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you experience painful red eyes with loss of vision after taking BUSCOPAN 0,1 % syrup, stop taking it and tell your doctor immediately. You may have an eye problem called glaucoma and need urgent medical attention.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Skin reactions such as hives, itching, rash or patchy red skin.
- Increased heart rate, slowing of the heart rate followed by increased heart rate with faster or irregular heartbeats, also called palpitations, and changes in the way the heart beats.
- Problems emptying the bladder.

Other side effects that do not normally need medical treatment:

- Dry mouth.
- Making less sweat than usual.
- Dryness of the skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256 3700 (tel), or
- SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of BUSCOPAN 0,1 % syrup.

5. How to store BUSCOPAN 0,1 % syrup

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BUSCOPAN 0,1 % syrup contains:

The active substance is hyoscine butylbromide.

Each 5 mL of syrup contains 5 mg of the active ingredient hyoscine butylbromide.

The solution is preserved with 0,08 % sorbic acid.

The other ingredients are: saccharin sodium, hydroxyethylcellulose, banana flavour and water purified.

What BUSCOPAN 0,1 % syrup looks like and contents of the pack:

A clear colourless to slightly yellow thick liquid with a banana odour.

Amber glass bottle of 100 mL with a white tamper-evident closure.

Holder of certificate of registration

Opella Healthcare South Africa (Pty) Ltd

4th Floor, Building I, Hertford Office Park,

90 Bekker Road, Midrand, 1652

Tel: 011 256 3700

This leaflet was last revised in

13 April 2022

Registration number

Z/11.2/93

Date of registration

18 March 1993

Approved Professional Information for BUSCOPAN® 10 mg tablets

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

BUSCOPAN® 10 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains hyoscine butylbromide 10 mg.

Contains sugar: 41,2 mg sucrose per tablet.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

White sugar-coated biconvex tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BUSCOPAN is used in the treatment of conditions associated with gastrointestinal spasm.

4.2 Posology and method of administration

Posology

Adults:

1 tablet 3 times daily. The dose can be increased at the discretion of the medical practitioner up to 2 tablets 4 times daily if necessary.

Children 6 – 12 years:

1 tablet 3 times daily.

The tablets should be swallowed whole with adequate liquid and not be chewed.

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

Special populations

Paediatric population:

For infants and children under 6 years BUSCOPAN 0,1 % syrup (containing 5 mg hyoscine butylbromide per 5 mL) is available.

4.3 Contraindications

BUSCOPAN is contraindicated in:

- patients who have demonstrated prior hypersensitivity to hyoscine butylbromide or any other component of the product (see section 6.1)
- myasthenia gravis
- mechanical stenosis in the gastrointestinal tract
- paralytic or obstructive ileus
- megacolon
- narrow angle glaucoma
- porphyria
- enlarged prostate
- fever
- tachycardia.

4.4 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, medical advice should immediately be sought.

Because of the potential risk of anticholinergic complications, caution should be used in patients prone to narrow angle glaucoma as well as in patients susceptible to intestinal or urinary outlet obstructions and in those inclined to tachyarrhythmia.

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 medicines 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 whilst or after taking Buscopan.

Caution is advised in patients with impaired metabolic, liver or kidney function, as adverse central nervous system effects may be more likely in these patients.

Cases of anaphylaxis including episodes of shock have been observed.

As the tablet coat contains sucrose (41,2 mg), patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take BUSCOPAN.

4.5 Interaction with other medicines and other forms of interaction

The anticholinergic effect of medicines such as tri- and tetracyclic antidepressants, antihistamines, quinidine, amantadine, antipsychotics (e.g. butyrophenones, phenothiazines), 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 medicines on the gastrointestinal tract.

The tachycardic effects of beta-adrenergic medicines may be enhanced by BUSCOPAN.

BUSCOPAN should be used with caution in patients receiving other central depressants concomitantly as central nervous system depression may be enhanced.

4.6 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. As a precautionary measure BUSCOPAN is not recommended during pregnancy.

Breastfeeding

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.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. Because of possible visual accommodation disturbances patients should not drive or operate machinery if affected.

4.8 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 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000); not known (cannot be estimated from the available data).

Immune system disorders:

Not known*: anaphylactic shock, anaphylactic reactions, dyspnoea, other hypersensitivity

Cardiac disorders:

Uncommon: tachycardia

Not known: bradycardia followed by tachycardia with palpitations and arrhythmias

Gastrointestinal disorders:

Uncommon: dry mouth

Skin and subcutaneous tissue disorders:

Uncommon: skin reactions (e.g. urticaria, pruritus), abnormal sweating

Not known*: rash, erythema

Renal and urinary disorders:

Rare: urinary retention.

* This adverse reaction has been observed in post-marketing experience. With 95 % certainty, the frequency category is not greater than uncommon (3/1 368), 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 1 368 patients.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of BUSCOPAN is important. It allows continued monitoring of the benefit/risk balance of BUSCOPAN. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

- https://www.sahpra.org.za/Publications/Index/8, or to the
- Pharmacovigilance Unit at Sanofi at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

4.9 Overdose

Symptoms:

In case of overdose, anticholinergic effects may be observed.

Toxic doses cause tachycardia, rapid or stertorous respiration, hyperpyrexia, restlessness, confusion and excitement, and hallucinations passing into delirium. A rash may appear on the face and upper trunk. In severe intoxication depression of the central nervous system may occur with hypertension or circulatory failure and respiratory depression. Quaternary ammonium anticholinergic medicines such as BUSCOPAN usually have some ganglion-blocking activity so that high doses may cause postural hypotension; in toxic doses non-depolarising neuro-muscular block may be produced.

Therapy:

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hyoscine butylbromide belongs to the medicine class A 11.2 Gastro-intestinal antispasmodics and cholinolytics (anticholinergics).

Hyoscine butylbromide is a quaternary ammonium anticholinergic medicine that acts at the parasympathetic ganglia in the walls of the viscera where it exerts a specific antispasmodic action on the smooth muscle of the gastrointestinal, biliary and urinary tracts.
As a quaternary ammonium derivative, hyoscine butylbromide does not readily pass the blood-brain barrier to enter the central nervous system.

5.2 Pharmacokinetic properties

Absorption:

As a quaternary ammonium compound, hyoscine butylbromide is highly polar and hence only partially absorbed following oral (8 %) or rectal (3 %) administration. After oral administration of single doses of hyoscine butylbromide in the range of 20 to 400 mg, mean peak plasma concentrations between 0,11 ng/mL and 2,04 ng/mL were found at approximately 2 hours. In the same dose range, the observed mean $AUC_{0\text{-}tz}$-values varied from 0,37 to 10,7 ng h/mL. The median absolute bioavailabilities of different dosage forms, i.e. coated tablets, suppositories and oral solution, containing 100 mg of hyoscine butylbromide each were found to be less than 1 %.

Distribution:

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:

Following oral administration of single doses in the range of 100 to 400 mg, the terminal elimination half-lives ranged from 6,2 to 10,6 hours. The main metabolic pathway is the hydrolytic cleavage of the ester bond. Orally administered hyoscine butylbromide is excreted in the faeces and in the urine. Studies in man show that 2 to 5 % of radioactive doses is eliminated renally after oral, and 0,7 to 1,6 % after rectal administration. Approximately 90 % of recovered radioactivity can be found in the faeces after oral administration. The urinary excretion of hyoscine butylbromide is less than 0,1 % of the dose. The mean apparent oral clearances after oral doses of 100 to 400 mg range from 881 to 1 420 L/min, whereas the corresponding volumes of distribution for the same range vary from 6,13 to 11,3 x 10^5 L, probably due to very low systemic availability. 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Dibasic calcium phosphate

Maize starch, starch soluble

colloidal silica

Tartaric acid

Stearic acid.

Tablet coating:

Polyvidone

Sucrose

Talc

Acacia

Titanium dioxide

Polyethylene glycol 6000

Carnauba wax

Beeswax white.

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 30 °C.

6.5 Nature and contents of container

PVC/Aluminium blister strips of 10 or 20 tablets packed into cartons of 10, 20 or 100 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Opella Healthcare South Africa (Pty) Ltd

4th Floor, Building I, Hertford Office Park,

90 Bekker Road, Midrand, 1652

8. REGISTRATION NUMBER

E 501 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Old medicine

10. DATE OF REVISION OF THE TEXT

19 April 2022

Approved Patient Information Leaflet for BUSCOPAN® 10 mg tablets

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

BUSCOPAN® 10 mg tablets

Hyoscine butylbromide

Contains sugar: 41,2 mg sucrose per tablet.

Read all of this leaflet carefully because it contains important information for you.

BUSCOPAN 10 mg tablets are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use BUSCOPAN 10 mg tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

4. What BUSCOPAN 10 mg tablets is and what it is used for

Hyoscine butylbromide belongs to a group of medicines called antispasmodics (medicines that relax the cramping muscles of your stomach and bowel).

BUSCOPAN 10 mg tablets are used in the treatment of conditions associated with gastrointestinal spasm, that is, to relieve cramps in the muscles of the stomach and gut.

5. What you need to know before you take BUSCOPAN 10 mg tablets

Do not take BUSCOPAN 10 mg tablets:

- if you are hypersensitive (allergic) to hyoscine butylbromide or any of the other ingredients (listed in section 6)
- if you have myasthenia gravis (a very rare muscle weakness problem)
- if you have suspected or confirmed blockage of the bowel
- if you have a condition where the bowel is blocked and does not work properly (paralytic or obstructive ileus)
- if you have a very enlarged bowel (megacolon)
- If you have glaucoma (an eye problem with increased pressure in the eye)
- if you have porphyria (disturbances of metabolism that can be seen as disorders of the skin or other organs)
- if you have an enlarged prostate
- if you have a fever

- if you have tachycardia (fast heartbeat)
- if you have rare hereditary (inherited) conditions that may be incompatible with an ingredient in BUSCOPAN 10 mg tablets, namely sugar. Please refer to "**BUSCOPAN 10 mg tablets contain sugar**".

Warnings and precautions

Take special care with BUSCOPAN 10 mg tablets:

Consult your doctor, pharmacist or other health care provider straight away:

- If you have severe, unexplained abdominal (belly) pain that persists or worsens or occurs together with fever, nausea (feeling sick), vomiting, changes in your bowel movements, abdominal (belly) tenderness, low blood pressure, fainting or blood in your bowel movements.

Consult your doctor, pharmacist or other health care provider before taking BUSCOPAN 10 mg tablets:

- if you tend to have a very fast heart rate or other heart problems
- if you have a tendency to blockage problems of the gut or urinary tract or if you have difficulty or pain passing water (urine) such as men with prostate problems
- if you are prone to glaucoma (increased pressure in the eye)
- if you have been treated by a doctor for a severe sweating problem
- if you have a fever
- if you have abnormal liver or kidney function.

Other medicines and BUSCOPAN 10 mg tablets

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

BUSCOPAN 10 mg tablets can interfere with some other medicines, in particular:

- Antihistamines – used to treat hay fever and other allergies.
- Tricyclic or tetracyclic antidepressant medicines – used to treat depression.
- Quinidine or disopyramide – used to control your heartbeat.
- Amantadine – used for Parkinson's disease and flu.
- Antipsychotic medicines such as butyrophenones or phenothiazines – used to treat severe mental illness such as schizophrenia.
- Tiotropium, ipratropium or atropine-like medicines – medicines inhaled to treat breathing problems.
- Dopamine antagonists such as metoclopramide for feeling nauseous.
- Beta-adrenergic medicines such as salbutamol for asthma.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not use BUSCOPAN 10 mg tablets if you are pregnant or breastfeeding your baby.

Driving and using machines

Some people may have temporary blurring of vision while taking BUSCOPAN 10 mg tablets. If this happens to you, wait until your vision returns to normal before driving or using any tools or machines.

BUSCOPAN 10 mg tablets contain sugar

One BUSCOPAN sugar-coated tablet contains 41,2 mg of sugar, equal to 411,8 mg of sugar per maximum recommended daily dose, which is 10 tablets. Patients with the rare hereditary condition of fructose intolerance should not take BUSCOPAN 10 mg tablets.

6. How to take BUSCOPAN 10 mg tablets

Always take BUSCOPAN 10 mg tablets exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- Adults and adolescents over 12 years of age: 1 – 2 tablets 3 to 4 times daily.
- Children 6 – 12 years of age: 1 tablet 3 times daily.

Swallow the tablets whole with enough liquid like water.

Do not crush or chew the tablets.

BUSCOPAN 10 mg tablets should not be taken on a continuous daily basis or for long periods without investigating the cause of the pain. You must see a doctor if your symptoms worsen or do not improve after 3 days.

For infants and children under 6 years, BUSCOPAN 0,1 % syrup (containing 5 mg hyoscine butylbromide per 5 ml) is available.

If you take more BUSCOPAN 10 mg tablets than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BUSCOPAN 10 mg tablets

If you miss a dose, take it as soon as you remember. If it is nearly time for your next dose, skip the missed dose and go back to your usual dosing schedule. Do not take a double dose to make up for forgotten individual doses.

7. Possible side effects

BUSCOPAN 10 mg tablets may have side effects.

Not all side effects reported for BUSCOPAN 10 mg tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BUSCOPAN 10 mg tablets, please consult your health care provider for advice.

If any of the following happens, stop taking BUSCOPAN 10 mg tablets and tell your doctor immediately or go to the casualty department at your nearest hospital. You may need urgent medical attention:

- Anaphylactic reaction and shock – this is a severe type of allergic reaction. The itchy rash may spread all over the body, as well as swelling. You may have difficulty in breathing and may lose consciousness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BUSCOPAN 10 mg tablets. You should seek urgent medical attention that may require hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice and of the following:

- If you experience painful red eyes with loss of vision after taking BUSCOPAN 10 mg tablets, stop taking it and tell your doctor immediately. You may have an eye problem called glaucoma and should seek urgent medical attention.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Skin reactions such as hives, itching, rash or patchy red skin.
- Increased heart rate, slowing of the heart rate followed by increased heart rate with faster or irregular heartbeats, also called palpitations, and changes in the way the heart beats.
- Problems emptying the bladder.

Other side effects that do not normally need medical treatment:

- Dry mouth.
- Making less sweat than usual.
- Dryness of the skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256 3700 (tel), or
- SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of BUSCOPAN 10 mg tablets.

8. How to store BUSCOPAN 10 mg tablets

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

9. Contents of the pack and other information

What BUSCOPAN 10 mg tablets contain

The active substance is hyoscine butylbromide.

Each tablet contains 10 mg of the active ingredient hyoscine butylbromide.

The other ingredients are dibasic calcium phosphate, maize starch, starch soluble, colloidal silica, tartaric acid, stearic acid, polyvidone, sucrose, talc, acacia, titanium dioxide, polyethylene glycol 6000, carnauba wax, beeswax white.

What BUSCOPAN 10 mg tablets look like and contents of the pack

White curved sugar-coated tablets.

Cartons containing blister packs of 10, 20 or 100 tablets.

Holder of certificate of registration

Opella Healthcare South Africa (Pty) Ltd

4th Floor, Building I, Hertford Office Park,

90 Bekker Road, Midrand, 1652

Tel: 011 256 3700

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