AUSTRALIAN PRODUCT INFORMATION– BUSCOPAN® AND BUSCOPAN® FORTE (HYOSCINE BUTYLBROMIDE)

1 NAME OF THE MEDICINE

HYOSCINE BUTYLBROMIDE

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

BUSCOPAN® tablets contain 10 mg hyoscine butylbromide per tablet.

Excipients of known effect: sucrose.

BUSCOPAN® FORTE tablets contain 20 mg hyoscine butylbromide per tablet.

Excipients of known effect: lactose monohydrate.

BUSCOPAN® ampoules contain 20 mg/1 mL hyoscine butylbromide per ampoule.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

BUSCOPAN® tablets: Round, white, biconvex sugar coated tablet.

BUSCOPAN® FORTE tablets: White round biconvex film-coated tablets. One side is marked "20", other side is marked "B".

BUSCOPAN® ampoules: Colourless clear solution.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

BUSCOPAN® and BUSCOPAN® FORTE tablets

Spasm of the gastrointestinal tract.

BUSCOPAN® ampoules

Spasm of the gastrointestinal tract, biliary spasm, renal spasm, diagnostic aid in radiology.

4.2 DOSE AND METHOD OF ADMINISTRATION

Tablets

Adults and children over 6 years:

2 BUSCOPAN® tablets (2 x 10mg) four times daily. OR

1 BUSCOPAN® FORTE tablet (1 x 20 mg) four times daily.

BUSCOPAN® tablets are not recommended for children under 6 years of age.

Ampoules

1 or 2 ampoules (20 or 40mg) by intramuscular or slow intravenous injection. A maximum daily dose of 100mg should not be exceeded.

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

4.3 CONTRAINDICATIONS

BUSCOPAN® are contraindicated in patients with:

- known hypersensitivity to hyoscine butylbromide or to any of the excipients of the product (excipients are listed under Section 6.1 List of excipients)
- mechanical stenosis in the gastrointestinal tract
- achalasia
- paralytic or obstructive ileus
- intestinal atony
- prostatic hypertrophy with urinary retention
- myasthenia gravis
- glaucoma
- pathological tachyarrhythmias
- megacolon

BUSCOPAN® should not be given to patients with porphyria as, according to a single report, it has been said to exacerbate the disease.

By intramuscular injection, BUSCOPAN® ampoules are contraindicated in patients being treated with anticoagulant drugs as intramuscular haematoma may occur. In these patients, intravenous routes may be used.

BUSCOPAN® and BUSCOPAN® FORTE tablets should not be used in patients with rare hereditary conditions that may be incompatible with the tablet excipients (see Section 4.4 Special warnings and precautions for use).

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.

Hyoscine may cause drowsiness: patients so affected should not drive or operate machinery. Patients should abstain from alcohol. However, as a quaternary ammonium compound with low lipid solubility, BUSCOPAN® cannot cross the blood/brain barrier easily and only rarely causes the central nervous system side effects associated with atropine and hyoscine.

After parenteral administration of BUSCOPAN®, patients with visual accommodation disturbances should not drive or operate machinery until vision has normalised.

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. Patients should be advised to seek urgent ophthalmological advice if they develop a painful, red eye with loss of vision after an injection of BUSCOPAN®.

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.

After parenteral administration, 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.

One BUSCOPAN® tablet contains 41.2 mg sucrose, resulting in 329.6 mg sucrose per maximum recommended daily dose. Patients with the rare hereditary condition of fructose intolerance should not take this medicine.

One BUSCOPAN® Forte tablet contains 138.5 mg lactose, resulting in 554 mg lactose per maximum recommended daily dose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, the Lapp lactose deficiency or glucose-galactose malabsorption, should not take this medicine.

Patients with cardiac conditions who are undergoing parenteral treatment with BUSCOPAN® ampoules should be monitored.

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.

Use in the elderly

No data available.

Paediatric use

Refer to section 4.2 for information on paediatric dosing.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

The anticholinergic effects of drugs such as amantadine, tri- and tetracyclic antidepressants, quinidine, antihistamines, antipsychotics, disopyramide, phenothiazines, belladonna alkaloids, other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) and MAO inhibitors etc, together with the tachycardia induced by beta-sympathomimetics, can be potentiated by BUSCOPAN®.

The concomitant administration of dopamine antagonists, such as metoclopramide, can reciprocally antagonise the effect on gastrointestinal tract motility.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

Category B2.

There is limited data from the use of hyoscine butylbromide in pregnant women.

As a precautionary measure, it is preferable to avoid the use of BUSCOPAN® during pregnancy.

Use in lactation

There is insufficient information on the excretion of BUSCOPAN® and its metabolites in human milk. As a precautionary measure, it is preferable to avoid the use of BUSCOPAN® during lactation.

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. 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.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Many of the listed adverse effects of BUSCOPAN® can be attributed to its anticholinergic properties. Anticholinergic side effects of BUSCOPAN® are generally mild and self limited.

Immune system disorders

Tablets: Anaphylactic reactions with episodes of dyspnoea and anaphylactic shock, skin reactions (e.g. urticaria, rash, erythema, pruritus), facial and periorbital swelling and other hypersensitivity reactions.

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

Eye disorders

Ampoules: Accommodation disorders, mydriasis, increased intraocular pressure.

Cardiac Disorders

Tablets and Ampoules: Tachycardia.

Vascular disorders

Ampoules: Decreased blood pressure, dizziness and flushing.

Gastrointestinal disorders

Tablets and Ampoules: Dry mouth.

Skin and subcutaneous tissue disorders

Tablets and Ampoules: Dyshidrosis, abnormal sweating.

Renal and urinary disorders

Tablets and Ampoules: Impaired micturition. Urinary retention.

Nervous system disorders

Very rarely in the national post marketing surveillance data base, there have been isolated reports following parenteral administration of coma, hallucinations, dystonia, confusion, agitation and dizziness from which the patient recovered after drug withdrawal and appropriate treatment. In very rare cases, dyspnoea has been reported.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems (Australia) or https://nzphvc.otago.ac.nz/reporting/ (New Zealand).

4.9 OVERDOSE

Symptoms

Serious signs of poisoning have not been observed in man. In case of overdose, anticholinergic symptoms such as urinary retention, dry mouth, reddening of the skin, inhibition of gastrointestinal motility, tachycardia, drowsiness and transient visual disorders may occur.

Toxicity data from studies in animals after parenteral administration suggest that the following may be possible: shock, Cheyne-Stokes respiration, respiratory paralysis, clonic spasms, paralysis of striated muscle, coma, paralytic ileus, bladder atony.

Management

After oral overdose, induce emesis, gastric lavage, activated charcoal followed by magnesium sulfate (15%). Supportive measures if necessary should be instituted. Symptoms of overdosage may respond to parasympathomimetics. Ophthalmological advice should be sought urgently in cases of glaucoma. Pilocarpine may be administered locally in patients with glaucoma. Sympathomimetics may be used for circulatory support. For mental excitation, diazepam.

Cardiovascular complications as a result of using this medicine should be treated according to usual therapeutic principles. In case of respiratory paralysis, intubation and assisted respiration. Catheterisation may be required for urinary retention. In addition, appropriate supportive measures should be used as required.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia) or the National Poisons Centre on 0800 POISON or 0800 764 766 (New Zealand).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

BUSCOPAN® is a quaternary ammonium compound which, as an anticholinergic agent, has a ganglion blocking component. Due to its anticholinergic action, BUSCOPAN® reduces the tone and peristalsis of smooth muscle in hollow organs with parasympathetic innervation. As a quaternary ammonium compound with low lipid solubility, it cannot pass the blood/brain

barrier easily and only rarely causes the central nervous system side effects associated with atropine and hyoscine.

BUSCOPAN® is a spasmolytic. The anticholinergic spasmolytic effect is based both on competitive inhibition of the parasympathetic activation of smooth muscle mediated through muscarinic receptors and, more markedly, through ganglionic blockade of neural transmission.

BUSCOPAN® is a powerful smooth muscle relaxant, effective when given by mouth or by injection. In the recommended dosages, BUSCOPAN® relieves smooth muscle spasm rapidly. Undesirable 'atropine-like' side effects such as blurred vision, palpitation or dry mouth are rare.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

BUSCOPAN® is poorly absorbed from the gastrointestinal tract and is rapidly distributed. The bioavailability of oral BUSCOPAN®, as calculated from plasma levels, is reported to be 0.13%.

Distribution

Upon oral administration hyoscine butylbromide concentrates especially in the tissue of the gastrointestinal tract, liver and kidneys. The high affinity of this agent to the tissue is reflected by the very short half-life, t-alpha of 3 minutes (distribution phase) of the blood levels, while the excretion rates are slow. Thus, in spite of the extremely low blood levels measurable over a short period of time, hyoscine butylbromide remains available at the site of action in the tissue in high concentrations.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

BUSCOPAN® tablets also contain calcium hydrogen phosphate, maize starch, soluble starch, colloidal anhydrous silica, tartaric acid, stearic acid and, in the tablet coating, sucrose, povidone, purified talc, acacia, titanium dioxide, macrogol 6000, carnauba wax and white beeswax.

BUSCOPAN® FORTE tablets also contain povidone, lactose, cellulose - microcrystalline, magnesium stearate and Opadry II white 85G18490.

BUSCOPAN® ampoules also contain sodium chloride and distilled water.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

BUSCOPAN® tablets

Store below 25°C

BUSCOPAN® FORTE tablets and BUSCOPAN® ampoules

Store below 30°C.

6.5 NATURE AND CONTENTS OF CONTAINER

BUSCOPAN® Tablets: Blister packs of 10*, 20 and 100

BUSCOPAN® FORTE Tablets: Blister packs of 10

BUSCOPAN® Ampoules (1mL): Boxes of 5

*Not sold in Australia

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

No data available.

CAS number

No data available.

7 MEDICINE SCHEDULE (POISONS STANDARD)

BUSCOPAN® Tablets, blister packs of 10, 20

(S2) Pharmacy Medicine;

BUSCOPAN® Tablets, blister packs of 100

(S4) Prescription Only Medicine

BUSCOPAN® FORTE Tablets

(S2) Pharmacy Medicine

BUSCOPAN® Ampoules

(S4) Prescription Only Medicine

8 SPONSOR

Sanofi Consumer Healthcare
87 Yarraman Place
Virginia QLD 4014

Sanofi-Aventis New Zealand Limited
Level 8, 56 Cawley Street,
Ellerslie Auckland 1051, New Zealand

9 DATE OF FIRST APPROVAL

BUSCOPAN® Tablets

3 August 1994
BUSCOPAN® FORTE Tablets
9 July 2008
BUSCOPAN® Ampoules
26 September 1991

10 DATE OF REVISION

22 September 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.8	Addition of abnormal sweating