SCHEDULING STATUS: S2

PROPRIETARY NAME (and dosage form):

Buscopan® 10 mg
tablets

COMPOSITION:
Each tablet contains hyoscine butylbromide 10 mg.
Other excipients: dibasic calcium phosphate, maize starch, starch soluble, aerosil 200, tartaric acid, stearic acid, polyvidone, sucrose, talc, acacia, titanium dioxide, polyethylene glycol 6000, carnauba wax, beeswax white. Contains sugar.

PHARMACOLOGICAL CLASSIFICATION:
A 11.2 Gastro-intestinal antispasmodics and cholinolytics (anticholinergics)

PHARMACOLOGICAL ACTION:
Hyoscine butylbromide is a quaternary ammonium anticholinergic agent 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 gastro-intestinal, biliary and urinary tracts.

As a quarternary ammonium derivative, hyoscine butylbromide does not readily pass the blood-brain barrier to enter the central nervous system.

INDICATIONS:
BUSCOPAN is used in the treatment of conditions associated with gastro-intestinal spasm.

CONTRA-INDICATIONS:
BUSCOPAN should not be used in patients who have demonstrated prior hypersensitivity to hyoscine butylbromide or any other component of the product.

Myasthenia gravis, porphyria, enlarged prostate. Closed angle glaucoma, paralytic ileus, pyloric stenosis and other mechanical stenoses/obstruction of the gastro-intestinal tract. Fever, tachycardia, megacolon.

In case of rare hereditary conditions that may be incompatible with an excipient of the product, namely sucrose (please refer also to "***Special precautions***"), the use of BUSCOPAN 10 mg tablets is contra-indicated.

WARNINGS:
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. Cases of anaphylaxis including episodes of shock have been observed.

INTERACTIONS:

The anticholinergic effect of medicines such as tricyclic antidepressants, antihistamines, quinidine, amantadine, disopyramide and other anticholinergics (eg. tiotropium, ipratropium) may be intensified by BUSCOPAN.

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

Concomitant treatment with dopamine antagonists e.g. metoclopramide may result in diminution of the effects of both medicines on the gastro-intestinal tract.

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

PREGNANCY AND LACTATION:
BUSCOPAN should not be used during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:
Adults and children over six years of age: 1 - 2 tablets 3 to 4 times daily. The dose can be increased at the discretion of the medical practitioner.
The tablets should be swallowed whole with a little water.

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

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Side-effects:
Many of the side-effects can be assigned to the anticholinergic properties of BUSCOPAN.

Immune system disorders:
Frequency between 0,01 and 0,1 %: hypersensitivity
Frequency between 0,1 and 1 %: skin reaction (urticaria)
The following side-effects have been reported and the frequencies are unknown: anaphylactic reaction, anaphylactic shock and dyspnoea.

Cardiac disorders:
Frequency between 0,1 and 1 %: tachycardia
The following side-effects have been reported and the frequencies are unknown: bradycardia followed by tachycardia with palpitations and arrhythmias.

Gastro-intestinal disorders:
Frequency between 0,1 and 1 %: dry mouth.
The following side-effects have been reported and the frequencies are unknown: Dryness of the mouth with difficulty in swallowing, thirst, as well as reduction in the tone and motility of the gastro-intestinal tract leading to constipation. Vomiting. Retrosternal pain may occur due to increased gastric reflux.

Skin and subcutaneous tissue disorders:
Frequency between 0,1 and 1 %: dyshidrosis.
The following side-effects have been reported and the frequencies are unknown: dryness of the skin.

Renal and urinary disorders:
Frequency between 0,01 and 0,1 %: urinary retention (a desire to urinate with the inability to do so).

Nervous system disorders:
The following side-effects have been reported and the frequencies are unknown: giddiness and staggering.

Eye disorders:
The following side-effects have been reported and the frequencies are unknown: dilatation of the pupils with loss of accommodation and photophobia, increased intra-ocular pressure.

Vascular disorders:
The following side-effects have been reported and the frequencies are unknown: flushing.

Special Precautions:
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.

One BUSCOPAN sugar-coated tablet of 10 mg contains 41,2 mg sucrose, resulting in 411,8 mg sucrose per maximum recommended daily dose (ten tablets per day). Patients with the rare hereditary condition of fructose intolerance should not take this medicine.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
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 agents 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.

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.

IDENTIFICATION:
White sugar-coated biconvex tablets.

PRESENTATION:

Blister packs of 10 or 100 tablets.

STORAGE INSTRUCTIONS:
Store at or below 30 °C. Keep out of the reach of children.

REGISTRATION NUMBER:
E 501 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
sanofi-aventis south africa (pty) ltd
2 Bond Street
1685, Midrand, SA

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
19 April 2013

BOTSWANA Reg. No.: B9304995	S3
NAMIBIA Reg. No.: 14/11.2/0423	NS1

VOUBILJET– BUSCOPAN 10 mg - TABLETTE

SKEDULERINGSTATUS: S2

EIENDOMSNAAM (en doseervorm):

Buscopan® 10 mg
tablette

SAMESTELLING:
Elke tablet bevat hiossienbutielbromied 10 mg.
Ander bestanddele: dibasiese kalsiumfosfaat, mieliestysel, oplosbare stysel, aerosil 200, wynsteensuur, stearіensuur, polividoon, sukrose, talk, akasia, titaandioksied, poliëtileenglikool 6000, palmwas, wit byewas. Bevat suiker.

FARMAKOLOGIESE KLASSIFIKASIE:
A 11.2 Maagdermkanaal: spasmolitiese en cholinolitiese middels (anticholinergiese middels)

FARMAKOLOGIESE WERKING:
Hiossienbutielbromied is ’n kwaternêre ammonium anticholinergiese middel wat werksaam is by die parasimpatiese ganglia in die dermwande, waar dit ’n spesifieke antispasmodiese werking op die gladde spiere van maagdermkanaal, gal- en urienweë uitoefen.

As kwaternêre ammoniumderivaat dring hiossienbutielbromied nie geredelik deur die bloedbreinskans om in die sentrale senuweestelsel te kom nie.

INDIKASIES:
BUSCOPAN word gebruik vir die behandeling van toestande geassosieer met maagdermkanaal spasma.

KONTRA-INDIKASIES:
BUSCOPAN moet nie gebruik word by pasiënte wat voorheen hipersensitiwiteit getoon het vir hiossienbutielbromied of enige ander komponent van die produk nie.

Miastenie gravis, porfirie, vergrote prostaat. Geslote-hoek gloukoom, paralitiese ileus, pilorus stenose en ander meganiese stenose/obstruksie van die maagdermkanaal. Koors, tagikardie, megakolon.

In geval van seldsame oorerflike toestande wat onverenigbaar kan wees met ’n bestanddeel van die produk, naamlik sukrose (kyk asseblief ook by “***Spesiale voorsorgmaatreëls***”), is die gebruik van BUSCOPAN 10 mg tablette teenaangedui.

WAARSKUWINGS:
Omdat daar ’n potensiële risiko is van anticholinergiese komplikasies, moet sorg geneem word by pasiënte wat geneig is tot nouhoek gloukoom, sowel as by pasiënte

wat vatbaar is vir intestinale of urinêre uitgang obstruksies en in diegene wat neig tot tagi-aritmie. Gevalle van anafilakse, insluitend episodes van skok, is waargeneem.

INTERAKSIES:
Die anticholinergiese effek van medisyne soos trisikliese antidepressante, antihistamiene, kinidien, amantadien, disopiramied en ander anticholinergiese middels (bv. tiotropium, ipratropium) kan deur BUSCOPAN versterk word.

Die tagikardiese effekte van beta-adrenergiese middels kan deur BUSCOPAN versterk word.

Gesamentlike behandeling met dopamien antagoniste, bv. metoklopramied, kan lei tot vermindering in die effek van albei hierdie medisyne op die maagdermkanaal.

BUSCOPAN moet met versigtigheid gebruik word by pasiënte wat ander sentrale onderdrukkende middels gesamentlik gebruik, aangesien sentrale senuweestelsel onderdrukking versterk kan word.

SWANGERSKAP EN LAKTASIE:
BUSCOPAN moet nie tydens swangerskap en laktasie gebruik word nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes en kinders ouer as ses jaar: 1 - 2 tablette 3 tot 4 keer per dag. Die dosis kan verhoog word volgens die diskresie van die mediese praktisyn.
Die tablette moet heel ingesluk word met ’n bietjie water.

Vir babas en kinders onder 6 jaar is BUSCOPAN 0,1 % stroop (wat 5 mg hiossienbutielbromied per 5 ml bevat) beskikbaar.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Newe-effekte:
Baie van die newe-effekte kan toegeskryf word aan die anticholinergiese eienskappe van BUSCOPAN.

Immuunstelsel siektes:
Frekwensie tussen 0,01 en 0,1 %: hipersensitiwiteit
Frekwensie tussen 0,1 en 1 %: velreaksie (urtikarie)
Die volgende newe-effekte is aangemeld en die frekwensies is onbekend: anafilaktiese reaksie, anafilaktiese skok en dispnee.

Hartsiektes:
Frekwensie tussen 0,1 en 1 %: tagikardie
Die volgende newe-effekte is aangemeld en die frekwensies is onbekend: bradikardie, gevolg deur tagikardie met hartkloppings en aritmie.

Maagdermkanaalsiektes:
Frekwensie tussen 0,1 en 1 %: droë mond.
Die volgende newe-effekte is aangemeld en die frekwensies is onbekend: Droogheid van die mond en probleme om te sluk, dors en ook vermindering in die tonus en motiliteit van die maagdermkanaal met gevolglike hardlywigheid. Braking. Retrosternale pyn kan voorkom te wyte aan verhoogde maagrefluks.

Vel- en onderhuidse weefselsiektes:
Frekwensie tussen 0,1 en 1 %: dishidrose.
Die volgende newe-effekte is aangemeld en die frekwensies is onbekend: droogheid van die vel.

Nier- en urienwegsiektes:
Frekwensie tussen 0,01 en 0,1 %: urienweg retensie (’n drang om te urineer, met onvermoë om dit te doen).

Senuweestelselsiektes:
Die volgende newe-effekte is aangemeld en die frekwensies is onbekend: duiseligheid en steiering.

Oogsiektes:
Die volgende newe-effekte is aangemeld en die frekwensies is onbekend: verwyding van die pupille met verlies aan akkommodasie en fotofobie, verhoogde binne-oogdruk.

Vaatsiektes:
Die volgende newe-effekt is aangemeld en die frekwensie is onbekend: gloede.

Spesiale voorsorgmaatreëls:
Versigtigheid word aangeraai by pasiënte met belemmerde metaboliese, lewer- of nierfunksie, aangesien ongunstige sentrale senuweestelsel effekte meer waarskynlik by hierdie pasiënte kan voorkom.

Een BUSCOPAN suikerbedekte tablet van 10 mg bevat 41,2 mg sukrose, wat 411,8 mg sukrose per maksimum aanbevole daaglikse dosis (tien tablette per dag) lewer. Pasiënte met die seldsame oorerflike afwyking van fruktose-intoleransie moet nie hierdie medisyne neem nie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
In geval van oordosering, kan anticholinergiese effekte waargeneem word. Toksiese dosisse veroorsaak tagikardie, vinnige of roggelende asemhaling, hiperpireksie, rusteloosheid, verwarring en opgewondenheid en hallusinasies wat oorgaan tot ylhoofdigheid. ’n Uitslag kan op die gesig en bolyf verskyn. By erge intoksikasie kan onderdrukking van die sentrale senuweestelsel voorkom, met hipertensie of sirkulatoriese ineenstorting en asemhalingsonderdrukking. Kwaternêre ammonium anticholinergiese middels soos BUSCOPAN het gewoonlik ’n mate van ganglion-blokkerende werksaamheid, dus kan hoë dosisse posturale hipotensie veroorsaak; by toksiese dosisse kan nie-depolariserende neuromuskulêre blokkering volg.

Behandeling is simptomaties en ondersteunend. Indien nodig, kan parasimpatomimetiese medisyne toegedien word. Oftalmologiese raad moet dringend verkry word in geval van gloukoom. Kardiovaskulêre komplikasies moet volgens gewone terapeutiese beginsels behandel word. In geval van respiratoriese paralise kan kunsmatige asemhaling oorweeg word. Kateterisasie kan benodig word

vir urienweg retensie. Daarbenewens kan geskikte maatreëls toegepas word soos nodig.

IDENTIFIKASIE:
Wit suikerbedekte bikonvekse tablette.

AANBIEDING:
Stolpverpakkingstroke in kartonne met 10 of 100 tablette.

BERGINGSINSTRUKSIES:
Bewaar teen of benede 30 °C. Hou buite bereik van kinders.

REGISTRASIENOMMER:
E 501 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
sanofi-aventis south africa (edms) bpk
Bondstraat 2,
1685, Midrand, SA

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
19 April 2013