PATIENT INFORMATION LEAFLET

Read this entire leaflet carefully because it contains important information for you.
BUSCOPAN 10 mg tablets are available without a doctor's prescription, for you to treat your 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 pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

SCHEDULING STATUS: S2

1. WHAT BUSCOPAN 10 mg TABLETS CONTAIN

Each tablet contains 10 mg of the active ingredient hyoscine butylbromide.
The other ingredients are 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.

BUSCOPAN 10 mg tablets

2. WHAT BUSCOPAN 10 mg TABLETS ARE USED FOR

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

3. 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 ingredients. (Refer to "**WHAT BUSCOPAN 10 mg TABLETS CONTAIN**", above.)
- If you have myasthenia gravis (a very rare muscle weakness problem), porphyria (disturbances of metabolism that can be seen as disorders of the skin or other organs), enlarged prostate.
- If you have closed angle glaucoma (increased pressure in the eye), paralytic ileus (small bowel not working properly), pyloric stenosis (narrowing of the muscular outlet of the stomach) and other mechanical stenoses (abnormal narrowings)/blockages of the stomach or gut.
- If you have a fever, tachycardia (fast heart beat) or megacolon (a very enlarged bowel).
- Do not use BUSCOPAN 10 mg tablets if you have rare hereditary (inherited) conditions that may be incompatible with an ingredient in BUSCOPAN 10 mg tablets, namely sugar. Please refer to "**Take special care with BUSCOPAN 10 mg tablets**".

Take special care with BUSCOPAN 10 mg TABLETS:

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.

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

- If you have abnormal liver or kidney function.
- If you are prone to glaucoma (increased pressure in the eye).
- 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.

Pregnancy and Breast-feeding:

Do not use Buscopan 10 mg tablets if you are pregnant, likely to get pregnant or breast-feeding. If you are pregnant, likely to get pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:
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.

Taking other medicines with BUSCOPAN 10 mg tablets:
If you are taking other medicines on a regular basis, including medicines bought over the counter and complementary or traditional medicines, the use of BUSCOPAN 10 mg tablets with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other professional, for advice.

BUSCOPAN 10 mg tablets can interfere with some other medicines, in particular:
Antihistamines – used to treat hayfever and other allergies.
Tricyclic antidepressant medicines – used to treat depression.
Quinidine or disopyramide – used to control your heart beat.
Amantadine – used for Parkinson's disease and flu.
Tiotropium or ipratropium – medicines inhaled to treat breathing problems.
Dopamine antagonists such as metoclopramide for feeling nauseous.
Beta-adrenergic medicines such as salbutamol for asthma.

4. HOW TO TAKE BUSCOPAN 10 mg TABLETS

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

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

5. POSSIBLE SIDE-EFFECTS

BUSCOPAN 10 mg tablets may have side-effects. The following side-effects may happen:

If you get any of the side-effects described below stop taking BUSCOPAN 10 mg tablets and tell your doctor immediately. 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.

- 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 need urgent medical attention.

Less frequent side-effects
- Skin rash
- Increased heart rate, slowing of the heart rate followed by increased heart rate with faster or irregular heart beats, also called palpitations and changes in the way the heart beats.

- Allergic reactions – the signs may include skin rash and itching, wheezing and shortness of breath
- Problems emptying the bladder

Other side-effects that do not normally need medical treatment:
- Dry mouth with difficulty swallowing, thirst, constipation, vomiting, heartburn.
- Making less sweat than usual.
- Giddiness and staggering.
- Flushing.
- Dryness of the skin.

If any of these side-effects become troublesome, please consult your doctor, pharmacist or other healthcare professional.

Not all side-effects reported for BUSCOPAN 10 mg tablets are included in this leaflet. Should your general health worsen while taking BUSCOPAN 10 mg tablets, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF BUSCOPAN 10 mg TABLETS

Keep out of the reach and sight 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).

7. PRESENTATION OF BUSCOPAN 10 mg TABLETS

Cartons containing blister packs of 10 tablets.

8. IDENTIFICATION OF BUSCOPAN 10 mg TABLETS

White curved sugar-coated tablets.

9. REGISTRATION NUMBER

E 501 (Act 101/1965)

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE REGISTRATION HOLDER

sanofi-aventis south africa (pty) ltd
2 Bond Street,
1685, Midrand, SA
South Africa
Tel. No.: +27-11-256 3700

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

19 April 2013

Lees die hele pamflet deeglik deur, want dit bevat belangrike inligting vir jou.
BUSCOPAN is sonder ’n dokter se voorskrif beskikbaar aan jou, om jou siekte te behandel. Nogtans moet jy versigtig wees met die gebruik van BUSCOPAN 10 mg tablette, om die beste resultate daaruit te verkry.

- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil deurlees.
- Indien jy meer inligting of raad wil hê, vra jou apteker of dokter.
- Jy moet ’n dokter gaan spreek as jou simptome erger word, of nie binne 3 dae verbeter nie.

SKEDULERINGSTATUS: S2

Buscopan® 10 mg tablette

1. WAT BUSCOPAN 10 mg TABLETTE BEVAT

Elke tablet bevat 10 mg van die aktiewe bestanddeel hiossienbutielbromied.
Die ander bestanddele is dibasiese kalsiumfosfaat, mieliestysel, oplosbare stysel, aerosil 200, wynsteensuur, stearіensuur, polividoon, sukrose, talk, akasia, titaandioksied, poliëtileen glikool 6000, palmwas, wit byewas. Bevat suiker.

2. WAARVOOR BUSCOPAN 10 mg TABLETTE GEBRUIK WORD

BUSCOPAN word gebruik in die behandeling van toestande geassosieer met inwendige spasma van die maagdermkanaal, dit wil sê om krampe in die maag- en dermspiere te verlig.

3. VOORDAT JY BUSCOPAN 10 mg TABLETTE NEEM

Moenie BUSCOPAN 10 mg tablette neem nie:

- Indien jy hipersensitief (allergies) is vir hiossienbutielbromied of enige van die bestanddele. (Verwys na “**WAT BUSCOPAN 10 mg TABLETTE BEVAT**”, hierbo.)
- Indien jy miastenie gravis het (’n baie seldsame probleem met swak spiere), porfirie (versteuring van metabolisme, wat as vel- of orgaanversteurings waargeneem word), vergrote prostaat.
- Indien jy geslote-hoek gloukoom (’n oogprobleem) het, paralitiese ileus (dunderm werk nie behoorlik nie), pilorus stenose (vernouing van die spier by die uitgang van die maag) en ander meganiese stenose (abnormale vernouings)/blokkasies in die maag of derms.
- Indien jy koors, tagikardie (vinnige hartklop) of megakolon het (baie vergrote dikderm).
- Moenie BUSCOPAN 10 mg tablette gebruik as jy ’n seldsame oorerflike toestand het wat kan bots met ’n bestanddeel in die produk, naamlik suiker, nie. Verwys asseblief na “**Neem spesiale sorg met BUSCOPAN 10 mg tablette”**.

Neem spesiale sorg met BUSCOPAN 10 mg tablette:
Een BUSCOPAN suikerbedekte tablet bevat 41,2 mg suiker, gelyk aan 411,8 mg suiker per maksimum aanbevole daaglikse dosis, wat 10 tablette is. Pasiënte met die seldsame oorerflike toestand fruktose intoleransie moet nie BUSCOPAN 10 mg tablette neem nie.

Raadpleeg jou dokter, apteker of ander professionele gesondheidsorgkundige voordat jy BUSCOPAN 10 mg tablette neem:

- Indien jy abnormale lewer- of nierfunksie het.
- Indien jy geneig is tot gloukoom (verhoogde druk in die oog).
- Indien jy geneig is tot ’n baie vinnige harttempo of ander hartprobleme het.
- Indien jy ’n geneigdheid het om blokkasieprobleme te ondervind met jou derms of urienweg of indien jy pyn het as jy uriene passeer, soos mans met prostaatprobleme.

Swangerskap en borsvoeding:

Moenie BUSCOPAN 10 mg tablette gebruik as jy swanger is nie, moontlik swanger kan raak nie, of as jy borsvoed nie. Indien jy swanger is, dalk kan swanger raak of jou baba borsvoed, raadpleeg jou dokter, apteker of ander professionele gesondheidsorgkundige.

Bestuur en gebruik van masjinerie:
Sommige mense kan tydelike dowwe visie ervaar terwyl hulle BUSCOPAN 10 mg tablette neem. Indien dit met jou gebeur, wag tot jy weer normaal kan sien voordat jy ry of enige gereedskap of masjinerie gebruik.

Die neem van ander medisyne met BUSCOPAN:
Indien jy ander medisyne op ’n gereelde basis gebruik, insluitend medisyne wat oor die toonbank gekoop word en komplementêre of tradisionele medisyne, kan die gelyktydige gebruik van BUSCOPAN 10 mg tablette en hierdie medisyne ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige om advies.

BUSCOPAN 10 mg tablette kan inmeng met sommige ander medisyne, veral:
Antihistamiene – gebruik om hooikoors en ander allergieë te behandel.
Trisikliese anti-depressante medisyne – gebruik om depressie te behandel.
Kinidien of disopiramied– gebruik om jou hartklop te beheer.
Amantadien – gebruik vir Parkinson se siekte en griep.
Tiotropium of Ipratropium – medisyne wat ingeasem word om asemhalingsprobleme te behandel.
Dopamien antagoniste, soos metoklopramied, vir ’n naar gevoel.
Beta-adrenergiese medisyne, soos salbutamol inhaleerders vir asma.

4. HOE OM BUSCOPAN 10 mg TABLETTE TE NEEM

Volwassenes en adolessente bo 6 jaar oud: 1 – 2 tablette 3 tot 4 keer daagliks.
Die tablette moet heel ingesluk word met ’n bietjie water.

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

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, haas die pasiënt na die naaste hospitaal of gifbeheersentrum.

5. MOONTLIKE NEWE-EFFEKTE

BUSCOPAN 10 mg tablette kan newe-effekte hê. Die volgende newe-effekte kan voorkom:

Indien jy enige van hierdie newe-effekte wat hieronder beskryf word, ervaar, hou op om BUSCOPAN 10 mg tablette te neem en lig dadelik jou dokter daaroor in. Jy benodig dalk dringende mediese aandag.

- Anafilaktiese reaksie en skok – dit is ’n ernstige tipe allergiese reaksie. Die jeukerige uitslag kan oor die hele liggaam versprei en daar kan ook swelling wees. Jy kan moeilik asemhaal en bewussyn verloor.

- Indien jy pynlike, rooi oë met verlies aan visie ervaar nadat jy BUSCOPAN 10 mg tablette geneem het, hou op om dit te neem en lig jou dokter dadelik daaroor in. Jy kan

’n oogprobleem hê wat bekend staan as gloukoom en dringende mediese aandag benodig.

Newe-effekte wat minder dikwels voorkom:
- Veluitslag
- Verhoogde harttempo, vertraging van harttempo, gevolg deur verhoogde harttempo met vinniger of onreëlmatige hartkloppings, ook bekend as palpitasies en verandering in die manier waarop die hart klop.
- Allergiese reaksies– die tekens kan insluit veluitslag en jeuk, fluitende asemhaling en kortasem
- Probleme om blaas te ledig

Ander newe-effekte wat normaalweg nie mediese behandeling benodig nie:
- Droë mond met moeilike sluk, dors, hardlywigheid, braking, sooibrand.
- Sweet minder as gewoonlik.
- Duiseligheid en steiering.
- Gloede.
- Droogheid van die vel.

Indien enige van hierdie newe-effekte lastig word, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige.

Nie alle newe-effekte wat vir BUSCOPAN 10 mg tablette aangemeld is, word in hierdie inligtingsblad genoem nie. Indien jou algemene gesondheid versleg terwyl jy BUSCOPAN 10 mg tablette neem, moet jy asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige raadpleeg.

6. BERGING EN WEGDOENING VAN BUSCOPAN 10 mg TABLETTE
Hou buite die bereik en sig van kinders.

Bewaar teen of benede 30 °C.
Moenie hierdie medisyne neem na die vervaldatum wat op die karton voorkom nie. Neem ongebruikte medisyne terug na jou apteker. Moenie van ongebruikte medisyne ontslae raak deur dit in afvoerpype of rioolstelsels (bv. toilette) te gooi nie.

7. AANBIEDING VAN BUSCOPAN 10 mg TABLETTE
Stolpverpakkingstroke, in kartonne met 10 tablette.

8. IDENTIFIKASIE VAN BUSCOPAN 10 mg TABLETTE
Wit, geronde suikerbedekte tablette.

9. REGISTRASIENOMMER
E 501 (Wet 101/1965)

10. NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE REGISTRASIEHOUER
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11. DATUM VAN PUBLIKASIE VAN DIE PASIËNTINLIGTINGSBLAD
19 April 2013