PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S1**

SCOPEX TABLETS, 10 mg, film-coated tablets

Hyoscine Butylbromide

Contains sugar:

Lactose 32 mg

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

SCOPEX TABLETS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SCOPEX TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SCOPEX TABLETS with any other person.
- 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 10 days.

What is in this leaflet:

1. What SCOPEX TABLETS is and what it is used for

2. What you need to know before you take SCOPEX TABLETS

3. How to take SCOPEX TABLETS

4. Possible side effects

5. How to store SCOPEX TABLETS

6. Contents of the pack and other information

1. What SCOPEX TABLETS is and what it is used for

SCOPEX TABLETS contain hyoscine butylbromide, which is used in the treatment of conditions associated with gastrointestinal spasm.

2. What you need to know before you take SCOPEX TABLETS

Do not take SCOPEX TABLETS

- If you are hypersensitive (allergic) to hyoscine butylbromide or any of the other ingredients of SCOPEX TABLETS (listed in section 6).
- If you have enlarged prostate.
- If you have paralysis of intestinal muscles or narrowing of the opening from the stomach to the first part of the small intestine.
- If you have eye problems.
- If you have a fever.
- If you have muscle weakness problem called myasthenia gravis.
- If you have a very fast heart rate or other heart problems.
- If you have low or high blood pressure.
- If you develop a life-threatening allergic reaction (anaphylaxis).

Warnings and precautions

Special care should be taken with SCOPEX TABLETS:

- Do not take SCOPEX TABLETS if you have diarrhoea, fever or a very fast heart rate or enlarged bowel.
- In patients with ulcerative colitis its use may lead to ileus or megacolon, and its effects on lower oesophageal sphincter may exacerbate reflux.

Other medicines and SCOPEX TABLETS

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

SCOPEX TABLETS should not be taken together with

- Amantadine – medicine for Parkinson's disease and flu.
- Medicines for allergies and travel sickness called antihistamines
- Butyrophenones, phenothiazines and medicines for depression called tricyclic antidepressants
- The absorption of other medicines may also be affected due to reduction in gastric motility.
- The use of SCOPEX TABLETS may make you sleepy, which can be worsened by taking alcohol or other depressants.

SCOPEX TABLETS with food and drink and alcohol

The use of SCOPEX TABLETS may make you sleepy, which can be worsened by taking alcohol or other depressants.

Pregnancy, breastfeeding and fertility

Safety in pregnancy, fertility and lactation has not been established.

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 SCOPEX TABLETS.

Driving and using machines

- SCOPEX TABLETS may make you feel drowsy/sleepy.
- Do not drive because SCOPEX TABLETS could interfere with your ability to drive safely.
- Do not operate any tools or machines.
- Do not climb dangerous heights.

It is not always possible to predict to what extent SCOPEX TABLETS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SCOPEX TABLETS affects them.

SCOPEX TABLETS contains lactose

SCOPEX TABLETS contains lactose. Patients with rare hereditary conditions of lactose/fructose or galactose intolerance should not take SCOPEX TABLET.

SCOPEX TABLETS contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take SCOPEX TABLETS

Always take SCOPEX TABLETS exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is: Two tablets (20 mg) four times daily.

If you take more SCOPEX 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 SCOPEX TABLETS

Do not take a double dose to make up for forgotten doses.

If you stop taking SCOPEX TABLETS

Not applicable

4. Possible side effects

Not all side effects reported for SCOPEX TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SCOPEX TABLETS, please consult your doctor, pharmacist or other healthcare professional for advice.

Less frequent:

- Dryness of the mouth with difficulty in swallowing or talking
- Occasionally vomiting, thirst
- Redness and dryness of the skin
- Reduced heart rate followed by increased heart rate
- Irregular or fast heartbeat
- Being unable to pass urine

Frequency not known:

- Dilation of the black center of the eye, loss of the eye's ability to change the point of focus from a distant object to a near object and sensitivity to light.
- Confusion, dizziness and staggering may occur
- May cause low blood pressure and inability in a man to get an erection
- Reduced bronchial secretions (reduced fluids produced in the bronchial tubes)

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 or nurse. You can also report side effects to SAHPRA via the safety APP (Medsafety x SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SCOPEX TABLETS.

May also report to Adcock Ingram Limited using in the following:

Adcock.AEReports@adcock.com

5. How to store SCOPEX TABLETS

Store all medicine out of reach of children.

Store in airtight container at or below 25 °C.

Protect from light.

Do not use after expiry date stated on the label.

6. Contents of the pack and other information

What SCOPEX TABLETS contains:

SCOPEX TABLETS contains the active ingredient Hyoscine butylbromide.

Each film-coated tablet contains 10 mg of hyoscine butylbromide.

The other ingredients are, paraben blend, lactose, magnesium stearate, maize starch, Opadry II White 85F18422, Opaglos NA - 7150, purified talc.

What SCOPEX TABLETS looks like and contents of the pack

White, round, biconvex, coated tablet, odourless.

White polypropylene securitainers with white, LDPE closures containing 10 tablets.

Blisters using PVC film & printed aluminium foil of 10 tablets.

Holder of Certificate of Registration

Adcock Ingram Limited

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Erand Gardens Midrand,

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Customer care: 0860 ADCOCK / 232625

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Registration number

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Namibia: NS1 14/11.2/0140

Botswana: S2 B9323925

PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: **S1**

SCOPEX TABLETS, 10 mg, filmbedekte tablette

Hiossienbutielbromied

Bevat suiker:

Laktose 32 mg

Lees hierdie hele biljet noukeurig deur, want dit bevat belangrike inligting vir u.

SCOPEX TABLETS is beskikbaar sonder 'n doktersvoorskrif, vir u om 'n minder ernstige siekte mee te behandel. Nietemin moet u steeds SCOPEX TABLETS versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie SCOPEX TABLETS met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter spreek indien u simptome vererger of nie na 10 dae verbeter nie.

Wat is in hierdie biljet:

1. Wat SCOPEX TABLETS is en waarvoor dit gebruik word
2. Wat u moet weet voordat u SCOPEX TABLETS neem
3. Hoe om SCOPEX TABLETS te neem
4. Moontlike newe-effekte
5. Hoe om SCOPEX-TABLETTE te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat SCOPEX TABLETS is en waarvoor dit gebruik word

SCOPEX TABLETS bevat hiossienbutielbromied, wat gebruik word in die behandeling van toestande wat verband hou met gastro-intestinale spasma.

2. Wat u moet weet voordat u SCOPEX TABLETS neem

Moenie SCOPEX TABLETS neem nie

- Indien u hipersensitief (allergies) is vir hiossienbutielbromied of enige van die ander bestanddele van SCOPEX TABLETS (gelys in afdeling 6).
- Indien u vergrote prostaat het.
- Indien u verlamming van dermspiere het of vernouing van die opening van die maag na die eerste deel van die dunderm.
- Indien u oogprobleme het.
- Indien u koors het.
- Indien u ‘n spierswakheid probleem genaamd myasthenia gravis het.
- Indien u 'n baie vinnige hartspoed of ander hartprobleme het.
- Indien u lae of hoë bloeddruk het.
- Indien u 'n lewensgevaarlike allergiese reaksie (anafilakse) ontwikkel.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet gedra word met SCOPEX TABLETS:

- Moenie SCOPEX TABLETS neem indien u diarree, koors of 'n baie vinnige hartspoed of vergrote derm het nie.
- By pasiënte met ulseratiewe kolitis kan die gebruik daarvan lei tot ileus of megakolon, en die uitwerking daarvan op die onderste slukderm-sfinkter kan refluks vererger.

Ander medisyne en SCOPEX TABLETS

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

SCOPEX TABLETS moet nie saam met die volgende geneem word nie

- Amantadien – medisyne vir Parkinson se siekte en griep.
- Medisyne vir allergieë en reissiekte wat antihistamiene genoem word
- Butirofenone, fenotiasiene en medisyne vir depressie wat trisikliese antidepressante genoem word
- Die absorpsie van ander medisyne kan ook beïnvloed word as gevolg van vermindering in maagmotiliteit.
- Die gebruik van SCOPEX TABLETS kan u slaperig maak, wat vererger kan word deur alkohol of ander depressante te neem.

SCOPEX TABLETS met kos en drank en alkohol

Die gebruik van SCOPEX TABLETS kan u slaperig maak, wat vererger kan word deur die neem van alkohol of ander depressante.

Swangerskap, borsvoeding en vrugbaarheid

Veiligheid tydens swangerskap, vrugbaarheid en laktasie is nie vasgestel nie.

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u SCOPEX TABLETS neem.

Bestuur en gebruik van masjinerie

- SCOPEX TABLETS kan u lomerig/slaperig laat voel.
- Moenie bestuur nie, want SCOPEX TABLETS kan inmeng met u vermoë om veilig te bestuur.
- Moenie enige gereedskap of masjiene hanteer nie.
- Moenie gevaarlike hoogtes klim nie.

Dit is nie altyd moontlik om te voorspel in watter mate SCOPEX TABLETS met die daaglikse

aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waartoe SCOPEX TABLETS hulle beïnvloed nie.

SCOPEX TABLETS bevat laktose

SCOPEX TABLETS bevat laktose. Pasiënte met ‘n seldsame oorerflike toestande van laktose/fruktose of galaktose-onverdraagsaamheid moet nie SCOPEX TABLETS neem nie.

SCOPEX TABLETS bevat laktose wat 'n effek op die beheer van u bloedsuiker kan hê indien u diabetes mellitus het.

Indien u deur u dokter meegedeel is dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u hierdie medisyne neem.

3. Hoe om SCOPEX TABLETS te neem

Neem altyd SCOPEX TABLETS presies soos beskryf in hierdie biljet of soos u dokter of apteker u vertel het. Raadpleeg u dokter of apteker indien u nie seker is nie.
Die gewone dosis is: Twee tablette (20 mg) vier keer per dag.

Indien u meer SCOPEX TABLETS neem as wat u moes

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u vergeet om SCOPEX TABLETS te neem

Moenie 'n dubbele dosis neem om vergete dosisse op te maak nie.

Indien u ophou om SCOPEX TABLETS

Nie van toepassing nie

4. Moontlike newe-effekte

Nie alle newe-effekte wat vir SCOPEX TABLETS aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u SCOPEX TABLETS neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies.

Minder gereeld:

- Droogheid van die mond met probleme om te sluk of te praat
- Braak soms, dorsheid
- Rooiheid en droogheid van die vel
- Verlaagde hartspoed gevolg deur verhoogde hartklop
- Onreëlmatige of vinnige hartklop
- Onvermoë om te urineer

Frekwensie nie bekend nie:

- Verwyding van die swart middelpunt van die oog, verlies van die oog se vermoë om die fokuspunt van 'n verre voorwerp na 'n nabye voorwerp te verander en sensitiwiteit vir lig.
- Verwarring, duiseligheid en verbystering kan voorkom
- Kan lae bloeddruk en onvermoë vir ‘n man om 'n ereksie te kry, veroorsaak
- Verminderde bronchiale afskeidings (verminderde vloeistowwe wat in die bronchiale buise geproduseer word)

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter of apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aameld via die veiligheidstoep (Medsafety x SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur

newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van SCOPEX TABLETS te verskaf.

Kan ook aan Adcock Ingram Limited aanmeld deur die volgende te gebruik:

Adcock.AEReports@adcock.com

5. Hoe om SCOPEX-TABLETTE te bêre

Bêre alle medisyne buite bereik van kinders.

Bêre in lugdigte houer teen of benede 25 °C.

Beskerm teen lig.

Moenie gebruik ná die vervaldatum wat op die etiket vermeld word nie.

6. Inhoud van die verpakking en ander inligting

Wat SCOPEX TABLETS bevat:

SCOPEX TABLETS bevat die aktiewe bestanddeel Hiossienbutielbromied.

Elke filmbedekte tablet bevat 10 mg hiossienbutielbromied.

Die ander bestanddele is parabeenmengsel, laktose, magnesiumstearaat, mieliestysel, “Opadry” II Wit 85F18422, “Opaglos” NA - 7150, gesuiwerde talk.

Hoe SCOPEX TABLETS lyk en die inhoud van die verpakking

Wit, rond, bikonvekse, bedekte tablet, reukloos.

Wit polipropileen veiligheidshouers met wit, LDPE-deksels wat 10 tablette bevat. Stulpstroke met PVC-film en gedrukte aluminiumfoelie van 10 tablette.

Houer van Sertifikaat van Registrasie

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Hierdie biljet is mees onlangs hersien op

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Registrasienommer

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