Proposed patient information leaflet for BUSCOPAN COMPOSITUM 10 mg/250 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BUSCOPAN COMPOSITUM 10 mg/250 mg tablets

Hyoscine butylbromide and metamizole sodium monohydrate

Contains sugar: Each tablet contains 100,5 mg sucrose and 42,9 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking BUSCOPAN COMPOSITUM.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BUSCOPAN COMPOSITUM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BUSCOPAN COMPOSITUM is and what it is used for
2. What you need to know before you take BUSCOPAN COMPOSITUM
3. How to take BUSCOPAN COMPOSITUM
4. Possible side effects
5. How to store BUSCOPAN COMPOSITUM
6. Contents of the pack and other information

1. What BUSCOPAN COMPOSITUM 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). Metamizole sodium monohydrate is an analgesic (medicines that reduce pain).

BUSCOPAN COMPOSITUM are used in the treatment of acute, severe pain or spasms of, for example, the biliary tract (gall bladder and bile ducts) and the urinary tract.

2. What you need to know before you take BUSCOPAN COMPOSITUM

Do not take BUSCOPAN COMPOSITUM:

- If you are allergic (hypersensitive) to pyrazolone or pyrazolidines (eg metamizole, isopropylaminophenazone, propiphenazone, phenazone or phenylbutazone) or to scopolamine butylbromide or to any of the other ingredients of this medicine (listed in section 6).
- If you have ever experienced a serious skin reaction with BUSCOPAN COMPOSITUM.
- If you have reacted with a decrease in the number of white blood cells in the blood (agranulocytosis) after using any of these substances.
- If you have had symptoms of asthma, rhinitis (runny or blocked nose) or urticaria (reddish spots or hives on the skin that may itch) after taking aspirin, paracetamol or non-steroidal anti-inflammatory drugs, as there may be cross-sensitivity.
- If you have suffered from impaired bone marrow function, for example, after receiving chemotherapy, or if you have had blood diseases.
- If you have a genetic deficiency of glucose-6-phosphate-dehydrogenase.
- If you suffer from acute intermittent porphyria (a disorder of the metabolism of blood pigments that are part of haemoglobin).
- If you suffer from increased pressure in the eye.
- If you have an enlarged prostate with difficulty urinating.
- If you suffer from a narrowing of the gastrointestinal tract.
- If you suffer from paralytic or obstructive ileus (intestinal paralysis).
- If you suffer from increased heart rate (tachycardia).
- If you have megacolon (abnormally large colon).

- If you suffer from myasthenia gravis (a chronic disease characterised by varying degrees of muscle weakness).
- If you are in the last three months of pregnancy (see section “Pregnancy, breastfeeding and fertility”).
- If you suffer from granulocytopenia (a lack of white blood cells)
- If you suffer from asthma.

Warnings and precautions

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

- If severe abdominal (belly) pain of unknown origin persists or worsens, or presents with symptoms such as fever, nausea (feeling sick), vomiting (being sick), changes in bowel movements, pain in the abdomen (belly) on touching, low blood pressure, fainting or presence blood in your stool, you should see your doctor immediately.
- If you have any sign or symptom suggestive of agranulocytosis (decrease in white blood cells) such as high fever, chills, sore throat, inflammation of the mouth, nose or throat, lesions on the oral or genital mucosa that could indicate a decrease in the number of white blood cells in the blood or any other type of blood dyscrasia (alteration of blood components) such as general unwellness, infection, persistent fever, bruises, bleeding or paleness. In these cases, you should stop the treatment and consult your doctor immediately.
- If you suffer from asthma syndrome due to painkillers or intolerance to painkillers, bronchial asthma, chronic urticaria or if you are intolerant to dyes and/or preservatives or alcohol, as the risk of possible serious allergic reactions is greater.
- If you have any signs or symptoms suggestive of anaphylaxis/anaphylactic shock (dizziness, shortness of breath, rhinitis, swelling of the face (angioneurotic edema), drop in blood pressure, reddish spots on the skin of sudden appearance). In these cases, you should stop the treatment and consult your doctor immediately. The probability of developing anaphylactic shock is higher in certain predisposed patients, such as patients with asthma or allergies.

- If you have had an anaphylactic or immunological reaction (such as agranulocytosis) to BUSCOPAN COMPOSITUM, you are also at high risk of reacting in a similar way to other pyrazolones and pyrazolidines. If you have had an allergic reaction to metamizole, other pyrazolones and pyrazolidines, or other non-narcotic pain relievers, you should not take a medicine containing it again.
- If you have pre-existing problems of low blood pressure, if you have unstable circulation or if you have a high fever, since in these cases the risk of a sudden drop in blood pressure is greater.
- In the event of lesions on the skin or mucous membranes, discontinue treatment with this medicine and consult your doctor immediately.
- If you suffer from decreased kidney or liver function or if you are an elderly patient.
- If you have had bleeding from the stomach or intestines since this has been reported in patients treated with metamizole.
- If after using BUSCOPAN COMPOSITUM you experience pain and redness in the eye, with loss of vision, inform your ophthalmologist immediately, since then you may suffer from undiagnosed narrow-angle glaucoma (a disease that causes increased pressure in the eyes).

Serious skin reactions

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported in association with

BUSCOPAN COMPOSITUM treatment. Stop using BUSCOPAN COMPOSITUM and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4 “Possible side effects” below.

If you have ever developed any of these serious skin reactions, you must not resume treatment with BUSCOPAN COMPOSITUM at any time (see section 2 “Do not take BUSCOPAN COMPOSITUM”).

Liver problems

You should not take BUSCOPAN COMPOSITUM if you have previously taken any metamizole-containing medicines (as contained in BUSCOPAN COMPOSITUM) and had liver problems. If you are unsure talk to your doctor. Inflammation of the liver has been reported in patients taking metamizole with symptoms developing within a few days to a few months following the start of treatment.

Stop using BUSCOPAN COMPOSITUM and contact a doctor if you have symptoms of liver problems (see section 4 “Possible side effects).

If you take more BUSCOPAN COMPOSITUM than is recommended in the dosage section of this patient information, contact a health care provider immediately.

Children and adolescents

BUSCOPAN COMPOSITUM is not indicated for use in children and adolescents.

Other medicines and BUSCOPAN COMPOSITUM

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

Using BUSCOPAN COMPOSITUM at the same time may enhance the anticholinergic effect (such as dry mouth, constipation) of medicines for the treatment of depression (tricyclic and tetracyclic antidepressants), medicines for the treatment of allergies (antihistamines), medicines for treatment of some mental disorders (antipsychotics), medicines for the treatment of irregular heartbeat (quinidine, disopyramide), medicines for the treatment of virus infections and/or treatment of Parkinson's disease (amantadine) and other anticholinergic medicines (for example tiotropium, ipratropium and atropine-like compounds).

If it is taken together with dopamine antagonists (such as metoclopramide, used to treat vomiting, nausea and/or paralysis of stomach movements) it may decrease the effect of both medicines.

It can enhance the tachycardic effect of beta-adrenergic medicines (medicines used to treat asthma) and alter the effect of other medicines such as digoxin (medicine used to treat heart problems).

If it is taken together with cyclosporine (a medicine that reduces the immune reactions of the body) it can reduce the blood levels of cyclosporine and therefore these should be measured regularly.

If it is taken together with chlorpromazine (medicine to treat mental disorders) it can cause a drop in body temperature.

Metamizole can interact with medicines that help prevent the blood from clotting (oral anticoagulants), medicines for the treatment of high blood pressure, diuretics (captopril, triamterene) and medicines for the treatment of mental disorders (lithium).

If it is taken together with methotrexate (a medicine to treat cancer), the toxicity of methotrexate may increase and therefore the concomitant use of both medicines should be avoided, especially in the elderly.

Metamizole can affect the effectiveness of antihypertensives (medicines that lower blood pressure) and diuretics (medicines that increase fluid elimination).

BUSCOPAN COMPOSITUM should be used with caution in patients taking low-dose aspirin (as a cardiac protector), as metamizole may decrease the antiplatelet effect of aspirin.

BUSCOPAN COMPOSITUM should be used with caution if you are taking the following medicines, as metamizole can lower the blood levels of:

- Efavirenz (used to treat HIV).

- Methadone (used to treat chronic pain).
- Ciclosporin and tacrolimus (used to prevent organ rejection, following a transplant).
- Sertraline (used to treat depression).
- Valproate (used to treat epilepsy and bipolar disorder).

In diabetics, metamizole may affect some tests to control blood sugar levels (glucose oxidase test).

Co-administration of valproate with metamizole may decrease valproate blood levels, which may decrease the efficacy of valproate. Your doctor will monitor your clinical response (seizure or mood control) and consider monitoring valproate serum levels if needed.

Taking BUSCOPAN COMPOSITUM with alcohol

The effects of alcohol and BUSCOPAN COMPOSITUM can be enhanced if taken together.

Pregnancy, breastfeeding and fertility

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 take BUSCOPAN COMPOSITUM if you are in the last 3 months of pregnancy.

Driving and using machines

Vision disturbances and dizziness may occur during treatment. It must also be taken into account that at higher doses concentration and reactions may be affected, so driving, operating machinery and other dangerous activities should be avoided. This is especially true when you have consumed alcohol.

3. How to take BUSCOPAN COMPOSITUM

Do not share medicines prescribed for you with any other person.

Always take BUSCOPAN COMPOSITUM exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual adult dose is 1 – 2 tablets up to 3 times a day.

The tablets should not be chewed, but swallowed whole with water.

Your doctor will tell you how long your treatment with BUSCOPAN COMPOSITUM will last. Do not take for longer than ten days without consulting your doctor. If you have the impression that the effect of BUSCOPAN COMPOSITUM is too strong or too weak, tell your doctor or pharmacist.

The dosage may need to be reduced if you are elderly, in poor general health or if you have damaged liver or kidney function.

If you have damaged metabolic, liver or kidney function, tell your doctor, pharmacist or other health care provider before taking BUSCOPAN COMPOSITUM.

If you take more BUSCOPAN COMPOSITUM than you should:

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

Symptoms

Anticholinergic symptoms such as urinary retention (difficulty passing urine), dry mouth, redness of the skin, tachycardia (fast heartbeat), inhibition of gastrointestinal motility and vision disturbances may appear.

Nausea, vomiting, abdominal pain, deterioration of kidney function and on more rare occasions dizziness, drowsiness, coma, seizures and a drop in blood pressure or even shock and increased heart rate (tachycardia) may also appear. After the administration of very high doses, a red discoloration of the urine may occur, which disappears when treatment is stopped.

If you forget to take BUSCOPAN COMPOSITUM

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 COMPOSITUM can have side effects. Not all side effects reported for BUSCOPAN COMPOSITUM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BUSCOPAN COMPOSITUM, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking BUSCOPAN COMPOSITUM 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. An itchy rash may spread all over the body, as well as swelling of the hands, feet, ankles, face, lips and mouth or throat. You may have difficulty swallowing or breathing and may lose consciousness.
- Difficulty breathing, feeling faint or dizzy.
- Allergic and hypersensitivity reactions – the signs may include skin rash and itching, wheezing and shortness of breath.
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal

necrolysis) (see section 2 “Warnings and precautions”).

- Widespread rash, high body temperature (fever > 38 °C) and enlarged lymph nodes which is due to drug reaction with eosinophilia and systemic symptoms (DRESS) or drug hypersensitivity syndrome (see section 2 “Warnings and precautions”).

These are all very serious side effects. If you have them, you may have had a serious reaction to BUSCOPAN COMPOSITUM. 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:

- Asthma.
- Problems emptying the bladder or no production or passing of urine.
- Fever.
- Chills.
- Abnormal sweating.
- The inside of your mouth, nose or throat becomes painful.
- Increased heart rate or other changes to your heart rate or rhythm.
- Vomiting blood or blood in the bowel movements.
- If you experience painful red eyes with loss of vision after taking BUSCOPAN COMPOSITUM, stop taking it and tell your doctor immediately. You may have an eye problem called glaucoma and need urgent medical attention.
- Liver reactions, including nausea or vomiting, fever, feeling tired, loss of appetite, dark-coloured urine, light-coloured, faeces, yellowing of the skin or white part of the eyes, itching, rash or upper stomach pain. These symptoms may be signs of liver injury. See also section 2 “Warnings and precautions”.

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

Tell your doctor if you notice any of the following:

Common side effects

- Dry mouth.

Uncommon side effects:

- Red discoloration of the urine. This usually disappears when treatment is stopped.
- Flushing.

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 SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to the Pharmacovigilance Unit at CFAO at chcsa-za-safety@cfao.com.

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

5. How to store BUSCOPAN COMPOSITUM

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 COMPOSITUM contain:

The active substances are hyoscine butylbromide and metamizole sodium monohydrate.

Each tablet contains 10 mg of hyoscine butylbromide and 250 mg of metamizole sodium monohydrate.

The other ingredients are lactose, maize starch, gelatine, soluble starch, hydrochloric acid, magnesium stearate, povidone (polyvinylpyrrolidine), sucrose (sugar), talc, acacia, titanium dioxide, macrogol 6000 (polyethylene glycol 6000), carnauba wax.

What BUSCOPAN COMPOSITUM look like and contents of the pack:

Round, white, biconvex sugar-coated tablets.

Amber glass bottles of 20 or 100 sugar-coated tablets.

Holder of Certificate of Registration:

CFAO Healthcare South Africa (Pty) Ltd

Atrium on 5th, 6th Floor, Sandton City

Corner Maude & 5th Street

Sandton, Gauteng

2146

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ACCESS TO CORRESPONDING PROFESSIONAL INFORMATION

www.buscopan.co.za

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

BUSCOPAN COMPOSITUM 10 mg/250 mg tablette

Hiossienbutielbromied en natriummetamisoolmonohidraat

Bevat suiker: Elke tablet bevat 100,5 mg sukrose en 42,9 mg laktosemonohidraat.

Lees hierdie inligtingsblad noukeurig deur voordat jy begin om BUSCOPAN COMPOSITUM te neem.

- Hou hierdie inligtingsblad. Dit mag nodig wees om dit weer te lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- BUSCOPAN COMPOSITUM is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit kan skadelik wees vir hulle, al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingsblad

1. Wat is BUSCOPAN COMPOSITUM en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy BUSCOPAN COMPOSITUM neem
3. Hoe om BUSCOPAN COMPOSITUM te neem
4. Moontlike newe-effekte
5. Hoe om BUSCOPAN COMPOSITUM te bewaar
6. Inhoud van die verpakking en ander inligting

7. Wat is BUSCOPAN COMPOSITUM en waarvoor word dit gebruik

Hiossienbutielbromied behoort aan ’n groep medisynes genaamd antispasmodiese middels

(medisynes wat die krampende spiere in die maag en derms laat ontspan).
Natriummetamisoolmonohidraat is ’n analgetikum (medisyne wat pyn verlig).
BUSCOPAN COMPOSITUM word gebruik in die behandeling van akute, hewige pyn of spasmas van byvoorbeeld die biliêre weg (galblaas en galbuise) en die urienweg.

8. Wat jy moet weet voordat jy BUSCOPAN COMPOSITUM neem

Moenie BUSCOPAN COMPOSITUM neem nie:

- Indien jy allergies (hipersensitief) is vir pirasoloon of pirasolidiene (bv. metamisool, isopropielaminofenasoon, propifenasoon, fenasoon of fenielbutasoon) of vir skopolamienbutielbromied, of vir enige van die ander bestanddele van hierdie medisyne (gelys by afdeling 6).
- Indien jy al ooit ’n ernstige velreaksie gehad het toe jy BUSCOPAN COMPOSITUM gebruik het.
- Indien jy voorheen nadat jy enige van hierdie medisynes gebruik het, ’n afname in die aantal witbloedselle in jou bloed (agranulositose) ervaar het.
- Indien jy simptome van asma, rinitis (loopneus of toe neus) of urtikarie (rooierige kolle of galbulte op die vel, wat mag jeuk) gehad het nadat jy aspirien, parasetamol of niesteroïdale antiinflammatoriese middels geneem het, aangesien kruissensitiwiteit kan voorkom.
- Indien jou beenmurgfunksie belemmer was, byvoorbeeld nadat jy chemoterapie ontvang het, of indien jy bloedsiektes gehad het.
- Indien jy weens ’n genetiese afwyking ’n gebrek aan die ensiem glukose-6-fosfaat-dehidrogenase het.
- Indien jy aan akute intermitterende porfirie ly (’n versteuring van die metabolisme van bloedpigmente wat deel vorm van hemoglobien).
- Indien jy aan verhoogde druk in die oog ly.
- Indien jou prostaat vergroot is en jy sukkel om te urineer.
- Indien daar ’n vernouing in jou spysverteringskanaal is.
- Indien jy aan paralitiese of obstruktiewe ileus ly (dermverlamming).
- Indien jou hartklop versnel is (tagikardie).

- Indien jy megakolon het (abnormaal groot dikderm).
- Indien jy aan myasthenia gravis ly (’n chroniese siekte wat deur wisselende grade van spierswakheid gekenmerk word).
- Indien jy in die laaste drie maande van jou swangerskap is (sien afdeling “Swangerskap, borsvoeding en vrugbaarheid”).
- Indien jy aan granulositopenie ly (’n tekort aan witbloedselle).
- Indien jy aan asma ly.

Waarskuwings en voorsorgmaatreëls

Konsulteer dadelik jou dokter, apteker of ander gesondheidsorgverskaffer:

- Indien hewige abdominale pyn (maagpyn) waarvan die oorsprong onbekend is, aanhou of vererger, of presenteer saam met simptome soos koors, naarheid (voel mislik), braking (gooi op), veranderings in ontlasting, pyn wanneer die buik aangeraak word, lae bloeddruk, floute of bloed in die stoelgang, moet jy onmiddellik jou dokter gaan spreek.
- Indien jy enige teken of simptoom het wat op agranulositose (afname in witbloedselle) mag dui, soos hoë koors, kouekoors, seer keel, inflammasie van die mond, neus of keel, letsels op die slymvliese van die mond of geslagsdele, wat ’n afname in die aantal witbloedselle in die bloed of enige ander bloeddiskrasie (wysiging van komponente van die bloed) kan aandui, soos ’n algemene gevoel van ongesteldheid, infeksie, aanhoudende koors, kneusings, bloeding of bleekheid. In sulke gevalle moet jy die behandeling staak en onmiddellik jou dokter raadpleeg.
- Indien jy ly aan asma-sindroom weens pynstillers of onverdraagsaamheid vir pynstillers, brongiale asma, chroniese urtikarie of indien jy onverdraagsaam is vir kleurmiddels en/of preserveermiddels of alkohol, aangesien die risiko van moontlike ernstige allergiese reaksies groter is.
- Indien jy enige tekens of simptome het wat op anafilakse/anafilaktiese skok (duiseligheid, kortasemheid, rinitis, swelling van die gesig (angioneurotiese edeem), val in bloeddruk, rooierige kolle op die vel wat skielik verskyn) dui. In sulke gevalle moet jy die behandeling staak en onmiddellik jou dokter raadpleeg. Die waarskynlikheid vir anafilaktiese skok is groter by

sekere vatbare pasiënte, soos pasiënte met asma of allergieë.

- Indien jy ’n anafilaktiese of immunologiese reaksie (soos agranulositose) op BUSCOPAN COMPOSITUM gehad het, het jy ook ’n hoë risiko om op ’n soortgelyke manier op ander pirasolone en pirasolidiene te reageer. Indien jy ’n allergiese reaksie op metamisool, ander pirasolone en pirasolidiene, of ander nie-narkotiese pynstillers gehad het, moet jy nie weer medisyne neem wat dit bevat nie.
- Indien jy voorafbestaande probleme met lae bloeddruk het, indien jy onstabiele bloedsomloop het of indien jy hoë koors het, aangesien die risiko van ’n skielike val in bloeddruk in hierdie gevalle groter is.
- In die geval van letsels op die vel of slymvliese, staak behandeling met hierdie medisyne en raadpleeg onmiddellik jou dokter.
- Indien jou nier- of lewerfunksie ingekort is of indien jy ’n bejaarde pasiënt is.
- Indien jy bloeding in jou maag of ingewande gehad het, aangesien dit by pasiënte wat met metamisool behandel word, gerapporteer is.
- Indien jy pyn en rooiheid in die oog met verlies aan visie ondervind nadat BUSCOPAN COMPOSITUM gebruik is, lig onmiddellik jou oftalmoloog in, aangesien jy aan ongediagnoseerde nouhoek-gloukoom kan ly (’n siekte wat verhoogde druk binne in die oë veroorsaak).

Ernstige velreaksies

Ernstige velreaksies, insluitende Stevens-Johnsonsindroom (SJS), toksiese epidermale nekrolise (TEN), en medisynereaksie met eosinofilie en sistemiese simptome (DRESS), is gepaardgaande met BUSCOPAN COMPOSITUM-behandeling gerapporteer. Hou op om BUSCOPAN COMPOSITUM te neem en kry onmiddellik mediese aandag indien jy enige van die simptome opmerk wat verband hou met hierdie ernstige velreaksies, beskryf in afdeling 4 “Moontlike newe-effekte” hier onder.

Indien jy ooit enige van hierdie ernstige velreaksies ontwikkel het, moet jy nooit weer behandeling met BUSCOPAN COMPOSITUM hervat nie (sien afdeling 2 “Moenie BUSCOPAN COMPOSITUM

neem nie”).

Lewerprobleme

Jy moenie BUSCOPAN COMPOSITUM neem indien jy voorheen enige medisynes wat metamisool bevat (soos in BUSCOPAN COMPOSITUM), geneem het en lewerprobleme gekry het nie. Indien jy onseker is, vra jou dokter. Inflammasie van die lewer is gerapporteer by pasiënte wat metamisool neem, met simptome wat binne ’n paar dae tot ’n paar maande ná aanvang van behandeling ontwikkel.

Hou op om BUSCOPAN COMPOSITUM te gebruik en kontak ’n dokter indien jy simptome van lewerprobleme kry (sien afdeling 4 “Moontlike newe-effekte”).

Indien jy meer BUSCOPAN COMPOSITUM neem as wat in die gedeelte rakende dosering in hierdie pasiëntinligtingsblad aanbeveel word, kontak onmiddellik ’n gesondheidsorgverskaffer.

Kinders en adolessente

BUSCOPAN COMPOSITUM word nie vir gebruik by kinders en adolessente aangedui nie.

Ander medisynes en BUSCOPAN COMPOSITUM

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisynes in.)

Gelyktydige gebruik van BUSCOPAN COMPOSITUM mag die anticholinergiese effek (soos droë mond, hardlywigheid) versterk van medisynes vir die behandeling van depressie (trisikliese en tetrasikliese antidepressante), medisynes vir die behandeling van allergieë (antihistamiene), medisynes vir die behandeling van sommige geestesteurings (antipsigotika), medisynes vir die behandeling van onegalige hartklop (kinidien, disopiramied), medisynes vir die behandeling van virusinfeksies en/of behandeling van Parkinson se siekte (amantadien) en ander anticholinergiese medisynes (byvoorbeeld tiotropium, ipratropium en atropien-tipe verbindings).

Indien dit saam met dopamienantagoniste geneem word (soos metoklopramied, gebruik om braking, naarheid en/of verlamming van dermbewegings te behandel) mag dit die effek van beide medisynes verswak.

Dit kan die tagikardiale effek van beta-adrenergiese medisynes (medisynes gebruik om asma te behandel) versterk en die effek van ander medisynes, soos digoksien (medisyne gebruik om hartprobleme te behandel), wysig.

Indien dit gepaardgaande met siklosporien geneem word (’n medisyne wat die liggaam se immuunreaksies verswak), kan dit die bloedvlakke van siklosporien verlaag en dit moet dus gereeld bepaal word.

Indien dit saam met chloorpromasien (medisyne om geestesteurings te behandel) geneem word, kan dit ’n val in liggaamstemperatuur veroorsaak.

Metamisool kan wisselwerking hê met medisynes wat help dat daar nie klonte in die bloed vorm nie (orale antikoagulante), medisynes vir die behandeling van hoë bloeddruk, diuretika (kaptopriel, triamtereen) en medisynes vir die behandeling van geestesteurings (litium).

Indien dit saam met metotreksaat (’n medisyne om kanker te behandel) geneem word, kan die toksisiteit van metotreksaat toeneem en gevolglik moet gepaardgaande gebruik van die medisynes vermy word, veral by bejaarde pasiënte.

Metamisool kan die effektiwiteit van antihipertensiewe medisynes (medisyne wat bloeddruk verlaag) en diuretika (medisyne wat uitskeiding van vloeistowwe laat toeneem) affekteer.

BUSCOPAN COMPOSITUM moet met omsigtigheid gebruik word by pasiënte wat laedosis-aspirien (vir hartbeskerming) neem, aangesien metamisool die antiplaatjie-effek van aspirien kan

verminder.

BUSCOPAN COMPOSITUM moet met omsigtigheid gebruik word indien jy enige van die volgende medisynes neem, aangesien metamisool die bloedvlakke daarvan kan verlaag:

- Efavirens (gebruik om MIV te behandel).
- Metadoon (gebruik om chroniese pyn te behandel).
- Siklosporien en takrolimus (gebruik om orgaanverwerping ná ’n oorplanting te voorkom).
- Sertralien (gebruik om depressie te behandel).
- Valproaat (gebruik om epilepsie en bipolêre steuring te behandel).

By diabete kan metamisool sommige van die toetse om bloedsuikervlakke te bepaal, affekteer (glukose-oksidasetoets).

Gepaardgaande toediening van valproaat en metamisool kan die vlak van valproaat in die bloed verlaag, wat die doeltreffendheid van valproaat kan verminder. Jou dokter gaan jou kliniese respons monitor (beheer van toevalle of gemoed) en dit oorweeg om serumvlakke van valproaat te monitor, indien nodig.

Neem van BUSCOPAN COMPOSITUM saam met alkohol

Die effekte van beide alkohol en BUSCOPAN COMPOSITUM kan versterk word indien dit terselfdertyd geneem word.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of gesondheidsorgverskaffer voordat jy hierdie medisyne neem.

Moenie BUSCOPAN COMPOSITUM neem indien jy in die laaste 3 maande van jou swangerskap

is nie.

Bestuur en gebruik van masjiene

Visiesteurings en duiseligheid kan tydens behandeling voorkom. Dit moet ook in ag geneem word dat konsentrasie en reaksietye teen hoër konsentrasies geaffekteer kan word, dus moet voertuigbestuur, hantering van masjinerie en ander gevaarlike aktiwiteite vermy word. Dit geld veral wanneer jy alkohol ingeneem het.

9. Hoe om BUSCOPAN COMPOSITUM te neem

Moenie medisynes wat vir jou voorgeskryf is, met enigiemand anders deel nie.

Neem BUSCOPAN COMPOSITUM altyd presies soos wat jou dokter of apteker vir jou gesê het. Vra gerus jou dokter of apteker indien jy onseker is.

Die gebruiklike volwasse dosis is 1 – 2 tablette tot 3 keer per dag.
Die tablette moenie gekou word nie, maar heel ingesluk word met water.

Jou dokter sal jou inlig hoe lank jou behandeling met BUSCOPAN COMPOSITUM gaan duur. Moet dit nie vir langer as tien dae gebruik sonder om vooraf jou dokter te konsulteer nie. Indien jy die indruk kry dat die uitwerking van BUSCOPAN COMPOSITUM te sterk of te swak is, sê dit vir jou dokter of apteker.

Dit mag nodig wees dat die dosering verlaag word indien jy ’n bejaarde pasiënt is, jou algemene gesondheid swak is of indien jou lewer- of nierfunksie belemmer is.

Indien jy belemmerde metaboliese, lewer- of nierfunksie het, lig jou dokter, apteker of ander gesondheidsorgverskaffer daaroor in voordat jy BUSCOPAN COMPOSITUM neem.

Indien jy meer BUSCOPAN COMPOSITUM neem as wat jy moet:

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Simptome

Anticholinergiese simptome soos urienterughouding (sukkel om te urineer), droë mond, rooiheid van die vel, tagikardie (vinnige hartklop), onderdrukking van beweeglikheid van die ingewandskanaal en visiesteurings mag verskyn.

Naarheid, braking, buikpyn, agteruitgang van nierfunksie kan voorkom, en in seldsame gevalle mag duiseligheid, lomerigheid, koma, toevalle en ’n val in bloeddruk of selfs skok en versnelde hartspoed (tagikardie) ook voorkom. Na toediening van baie hoë dosisse kan die urine rooi verkleur, wat weer verdwyn wanneer behandeling gestaak word.

Indien jy vergeet om BUSCOPAN COMPOSITUM te neem

Indien jy ’n dosis vergeet het, neem dit sodra jy onthou. Indien dit byna tyd is vir die volgende dosis, slaan die dosis wat jy vergeet het oor en gaan voort volgens jou gebruiklike skedule. Moenie ’n dubbele dosis neem om te vergoed vir die individuele dosisse wat oorgeslaan is nie.

10. Moontlike newe-effekte

BUSCOPAN COMPOSITUM kan newe-effekte hê. Nie alle newe-effekte wat vir BUSCOPAN COMPOSITUM gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou verswak of as jy enige ongunstige effekte ondervind terwyl jy BUSCOPAN COMPOSITUM neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg.

Indien enige van die volgende voorkom, hou op om BUSCOPAN COMPOSITUM te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal. Jy mag

dringend mediese bystand benodig:

- Anafilaktiese reaksie en skok – dit is ’n hewige soort allergiese reaksie. ’n Jeukende uitslag kan oor die hele liggaam versprei, sowel as swelling van die hande, voete, enkels, gesig, lippe en mond of keel. Jy kan sukkel om te sluk of asem te haal en kan jou bewussyn verloor.
- Sukkel om asem te haal, voel flou of duiselig.
- Allergiese en hipersensitiwiteitsreaksies – die tekens kan veluitslag en gejeuk, gehyg en kortasemheid insluit.
- Rooierige, plat kolle wat lyk soos teikens of sirkels op die romp, dikwels met blase in die middel, vel wat afskilfer, ulkusse in die mond, keel, neus, geslagsdele en oë. Hierdie ernstige veluitslae kan voorafgegaan word deur koors en griepagtige simptome (Stevens-Johnsonsindroom, toksiese epidermale nekrolise) (sien afdeling 2 “Waarskuwings en voorsorgmaatreëls”).
- Wydverspreide uitslag, hoë liggaamstemperatuur (koors > 38 °C) en vergrote limfknope weens medisynereaksie met eosinofilie en sistemiese simptome (DRESS) of medisyne-hipersensitiwiteitsindroom (sien afdeling 2 “Waarskuwings en voorsorgmaatreëls”).

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ondervind, mag jy ’n ernstige reaksie op BUSCOPAN COMPOSITUM gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Indien jy enige van die volgende opmerk, sê onmiddellik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Asma.
- Probleme om die blaas te ledig of geen urine word gevorm of uitgeskei nie.
- Koors.
- Kouekoors.
- Abnormale sweetafskeiding.
- Die binnekant van jou mond, neus of keel raak seer.

- Versnelde hartklop of ander veranderings in jou harttempo of -ritme.
- Braak bloed, of bloed in die stoelgang.
- Indien jy pynlike rooi oë met sigverlies ervaar nadat jy BUSCOPAN COMPOSITUM geneem het, hou op om dit te neem en sê onmiddellik vir jou dokter. Jy kan ’n oogprobleem genaamd gloukoom hê en dringend mediese sorg benodig.
- Lewerreaksies, insluitende naarheid of braking, koors, moegheid, aptytverlies, donkerkleurige urine, ligkleurige stoelgange, vergeling van die vel of wit deel van die oë, gejeuk, uitslag of pyn in die boonste deel van jou buik. Hierdie simptome kan tekens van lewerskade wees. Sien ook afdeling 2 “Waarskuwings en voorsorgmaatreëls”.

Hierdie is ernstige newe-effekte. Jy mag dringend mediese sorg benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat algemeen voorkom:

- Droë mond.

Newe-effekte wat nie algemeen voorkom nie:

- Rooi verkleuring van die urine. Dit verdwyn gewoonlik wanneer behandeling gestaak word.
- Blosing.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker daaroor in.

Rapportering van newe-effekte:

Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety-toepassing (Medsafety X SAHPRA) en eRapportering-platform (who-umc.org), wat op SAHPRA se webwerf beskikbaar is, of aan CFAO se Eenheid vir Farmakowaaksaamheid by chcsa-za-safety@cfao.com.

Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die veiligheid van BUSCOPAN COMPOSITUM te verskaf.

11. Hoe om BUSCOPAN COMPOSITUM te bewaar

Bewaar alle medisynes buite bereik van kinders.

Bêre by of onder 25 °C.

Moenie gebruik ná die vervaldatum wat op die karton voorkom nie.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) wegdoen nie.

12. Inhoud van die verpakking en ander inligting

Wat BUSCOPAN COMPOSITUM bevat:

Die aktiewe bestanddele is hiossienbutielbromied en natriummetamisoolmonohidraat.

Elke tablet bevat 10 mg hiossienbutielbromied en 250 mg natriummetamisoolmonohidraat.

Die ander bestanddele is laktose, mieliestysel, gelatien, oplosbare stysel, soutsuur, magnesiumstearaat, povidoon (polivinielpirrolidien), sukrose (suiker), talk, akasia, titaandioksied, makrogol 6000 (poliëtileenglikol 6000), carnaubawas.

Hoe BUSCOPAN COMPOSITUM lyk en inhoud van die verpakking:

Ronde, wit, bikonvekse, suikerbedekte tablette.

Amberkleurige glasbottels met 20 of 100 suikerbedekte tablette.

Houer van Registrasiesertifikaat:

CFAO Healthcare South Africa (Edms.) Bpk.

Atrium on 5th, 6de Vloer, Sandton City

h.v. Maude & 5de Straat

Sandton, Gauteng

2146

Hierdie inligtingsblad is laas hersien

05 Desember 2024

Registrasienommer

E/11.2/502

Datum van registrasie

01 September 1994

TOEGANG TOT OOREENSTEMMENDE PROFESSIONELE INLIGTING

www.buscopan.co.za