Approved Professional Information for Buscopan Compositum 20 mg/2,5 g injection

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

BUSCOPAN COMPOSITUM 20 mg/2,5 g injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml ampoule contains

Metamizole sodium monohydrate: 2500 mg

Hyoscine butylbromide: 20 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A clear, slightly yellowish solution free from physical impurities.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Acute, severe colicky pains of the biliary, urinary and gastro-intestinal tract.

4.2 Posology and method of administration

Posology

Not to be given to children under 12 months of age.

1 ampoule of 5 ml by slow intravenous injection; if possible the patient should be in a lying position. The injection should be given over at least 5 minutes.

If necessary the same dose may be repeated 2 to 3 times daily at intervals of several hours.

Should intravenous injection be impossible, the preparation may be given by intramuscular injection.

Method of administration

Not to be administered subcutaneously.

The administration of BUSCOPAN COMPOSITUM 20 mg/2,5 g injection should be under medical supervision and be monitored.

BUSCOPAN COMPOSITUM 20 mg/2,5 g injection should only be injected intravenously or intramusculary. Inadvertent intra-arterial use may cause necrosis in the distal vascular area.

Precaution

With intramuscular injection the following technique should be carefully observed:

Site of injection: Only in the upper, outer quadrant of the buttock.

Direction: Sagittally and directed towards the iliac crest.

Depth: A sufficiently long needle to ensure the injection reaches the muscle.

4.3 Contraindications

BUSCOPAN COMPOSITUM 20 mg/2,5 g injection is contra-indicated in:

- patients who have demonstrated prior hypersensitivity to pyrazolone or pyrazolidines (e.g., metamizole, isopropylaminophenazone, propyphenazone, phenazone or phenylbutazone), or to hyoscine butylbromide, or to any other component of the product included in section 6.1. This includes patients who developed agranulocytosis, for example, following use of one of these substances.
- patients with granulocytopenia.
- patients with known analgesic-induced asthma syndrome or known analgesic intolerance of the urticaria-angioedema type, i.e. patients who develop bronchospasm or other anaphylactoid reactions in response to salicylates, paracetamol or other non-narcotic analgesics such as diclofenac, ibuprofen, indomethacin or naproxen.

- the potential of cross-sensitivity with aspirin and other non-steroidal anti-inflammatory agents exists. BUSCOPAN COMPOSITUM 20 mg/2,5 g injection should not be given to patients in whom aspirin or other nonsteroidal anti-inflammatory drugs induce symptoms of asthma, rhinitis or urticaria.
- impaired bone marrow function (e.g., after treatment with cytostatic agents) or diseases of the haemopoietic system.
- genetic glucose-6-phosphate-dehydrogenase deficiency (risk of haemolysis).
- patients with acute intermittent hepatic porphyria (risk of triggering a porphyria attack).
- Glaucoma
- hypertrophy of the prostate with urinary retention
- mechanical stenosis in the gastrointestinal tract
- paralytic or obstructive ileus
- pronounced tachycardia
- megacolon
- myasthenia gravis
- three months of pregnancy (see section 4.6)
- asthma
- patients with existing arterial hypotension and unstable circulatory state
- in patients being treated with anticoagulant drugs as intramuscular injection, since intramuscular haematoma may occur. In these patients, the intravenous route may be used.
- subcutaneous injection (see section 4.2)
- intraarterial injection (see section 4.2 and 4.4)
- in case of rare hereditary conditions that may be incompatible with an excipient of the product (see section 4.4)
- the third trimester of pregnancy (see section 4.6)
- children under 12 months of age. This medicinal product it is not recommended in children nor adolescents (under 18 years old), as safety and efficacy is not demonstrated in these patients.
- patients with existing arterial hypotension and unstable circulatory state

- subcutaneous injection (see section 4.2)
- intraarterial injection (see section 4.2 and 4.4)
- in case of rare hereditary conditions that may be incompatible with an excipient of the product (see section 4.4)

4.4 Special warnings and precautions for use

Unexplained abdominal pain

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, appropriate diagnostic measures are needed to investigate the etiology of the symptoms.

Haematologic reactions (such as agranulocytosis or pancytopenia)

BUSCOPAN COMPOSITUM 20 mg/2,5 g injection contains metamizole, a derivative of pyrazolone, which presents a risk of agranulocytosis, which is rare but life-threatening (see section 4.8).

In the event of clinical signs of haematologic reactions (such as agranulocytosis, aplastic anaemia, thrombocytopenia or pancytopenia), treatment with BUSCOPAN COMPOSITUM 20 mg/2,5 g injection must be discontinued immediately and the blood count (including differential blood count) must be monitored until it has returned to normal (see section 4.8). Discontinuation of treatment must not be delayed until the results of the lab tests are available. All patients should be advised to immediately consult a physician if during treatment with BUSCOPAN COMPOSITUM 20 mg/2,5 g injection signs and symptoms occur which are suggestive of blood dyscrasia (e.g. general malaise, infection, persistent fever, bruising, bleeding or pallor).

Patients who show an immunological reaction such as agranulocytosis to BUSCOPAN COMPOSITUM 20 mg/2,5 g injection are also at high risk of responding similarly to other pyrazolones and pyrazolidines.

Anaphylactic/anaphylactoid reactions

When choosing the administration route, it should be borne in mind that parenteral administration of BUSCOPAN COMPOSITUM 20 mg/2,5 g injection presents a higher risk of anaphylactic or anaphylactoid reactions. The risk of potentially severe anaphylactoid reactions to BUSCOPAN COMPOSITUM 20 mg/2,5 g injection is markedly higher for patients with:

- analgesic-induced asthma syndrome or analgesic intolerance of the urticaria-angioedema type (see section 4.3)
- bronchial asthma, in particular in the presence of rhinosinusitis and nasal polyps
- chronic urticaria
- intolerance to colouring agents (e.g. tartrazine) and/or preservatives (e.g. benzoates)
- alcohol intolerance. These patients react to even minute amounts of alcoholic drinks with symptoms such as sneezing, watering eyes and severe facial flushing. Alcohol intolerance of this kind may be an indication of as yet undiagnosed analgesic-induced asthma syndrome (see section 4.3).

Metamizole may cause the rare, but life-threatening risk of shock (see section 4.8).

The likelihood of anaphylactic shock is greater in susceptible patients. Particular caution is therefore required when using BUSCOPAN COMPOSITUM 20 mg/2,5 g injection in patients with asthma or atopy.

Prior to administration of BUSCOPAN COMPOSITUM 20 mg/2,5 g injection, the patient must be questioned appropriately. In patients at high risk of anaphylactoid reactions, BUSCOPAN COMPOSITUM 20 mg/2,5 g injection should only be used after consideration of the potential risks in relation to the expected benefit. If BUSCOPAN COMPOSITUM 20 mg/2,5 g injection is administered in such cases, the patient must be monitored very closely and emergency standby guaranteed.

Patients who show an anaphylactic or other immunological reaction to BUSCOPAN COMPOSITUM 20 mg/2,5 g injection are also at high risk of responding similarly to other pyrazolones, pyrazolidines and other non-narcotic analgesics.

Isolated hypotensive reactions

BUSCOPAN COMPOSITUM 20 mg/2,5 g injection can cause hypotensive reactions (see section 4.8). These reactions may be dose-dependent and are more likely with parenteral rather than enteral administration.

The risk of such reactions is also increased in the case of:

- too rapid intravenous injection (see section 4.2)
- patient with e.g. previous arterial hypotension, volume depletion or dehydration, unstable circulation or incipient circulatory failure (such as patients with heart attack or polytrauma)
- patients with a high fever.

As a result, careful diagnosis and close monitoring is essential for these patients. Preventive measures (e.g., stabilization of the circulation) may be necessary in order to reduce the risk of hypotensive reactions. BUSCOPAN COMPOSITUM 20 mg/2,5 g injection requires close monitoring of the haemodynamic parameters when used in patients for whom a fall in blood pressure must be avoided at all costs, such as in the case of severe coronary artery disease or relevant stenosis of the cerebral blood vessels.

Severe skin reaction

Life-threatening skin reactions, such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) were reported under treatment of metamizole. If signs or symptoms of SJS or TEN develop (such as skin rash often progressive with blisters or mucosal injury), treatment with BUSCOPAN COMPOSITUM 20 mg/2,5 g injection must be discontinued immediately and never be reintroduced.

Patients should be advised of the signs and symptoms of these severe skin reactions, so that in case they develop, medical advice is sought, and these reactions can be monitored closely, particularly in the first weeks of treatment.

Gastrointestinal bleeding

Gastrointestinal bleeding has been reported in patients treated with metamizole. Many patients had concomitantly received other treatment (e.g., NSAIDs) associated with gastrointestinal bleeding, or used an overdose of metamizole.

Intraocular pressure

Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as hyoscine butylbromide in patients with undiagnosed and therefore untreated narrow angle glaucoma. Therefore, patients should be advised to seek urgent ophthalmological advice in case they should develop a painful, red eye with loss of vision after the injection of BUSCOPAN COMPOSITUM 20 mg/2,5 g injection

Risk associated with incorrect route of administration

When administered parenterally, attention should be paid to proper injection technique. Inadvertent intraarterial use may cause necrosis potentially leading to amputation in the distal vascular area.

Risk in specific populations

BUSCOPAN COMPOSITUM 20 mg/2,5 g injection should only be used after consideration of the benefit-risk ratio and appropriate precautions must be taken for elderly or patients with impaired renal or hepatic function (see section 4.2).

Caution is required when administering parenterally BUSCOPAN COMPOSITUM 20 mg/2,5 g injection to patients with a history of cardiovascular disease risk factors. Special monitoring is required in patient suffering from tachycardia.

Patients receiving BUSCOPAN COMPOSITUM 20 mg/2,5 g injection should be monitored for hypotension and tachycardia, especially those with a history of cardiac disease or hypertension.

Interference with laboratory tests

In diabetic patients the pyrazolone derivative can affect the enzymatic blood sugar assay by the glucose-oxidase method (GOD).

4.5 Interaction with other medicines and other forms of interaction

Methotrexate

Concomitant administration of BUSCOPAN COMPOSITUM 20 mg/2,5 g injection with methotrexate may increase blood toxicity of methotrexate particularly in elderly patients. Therefore, this combination should be avoided.

Chlorpromazine

Concomitant use of metamizole and chlorpromazine can cause severe hypothermia.

Acetylsalicylic acid

BUSCOPAN COMPOSITUM 20 mg/2,5 g injection can reduce the antiplatelet effect of acetylsalicylic acid if administered concomitantly. BUSCOPAN COMPOSITUM 20 mg/2,5 g injection should therefore be used with caution in patients who are taking low-dose acetylsalicylic acid for cardioprotection.

Bupropion

Blood levels of bupropion can be reduced by metamizole. Caution is therefore required if metamizole and bupropion are used concomitantly.

Cyclosporin

If BUSCOPAN COMPOSITUM 20 mg/2,5 g injection is taken concomitantly with cyclosporin, cyclosporin blood levels may be reduced and should therefore be monitored.

Medicines with anticholinergic effects

The anticholinergic effect of medicines such as tri- and tetracyclic antidepressants, antihistamines, antipsychotics, quinidine, amantadine, disopyramide and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by BUSCOPAN COMPOSITUM 20 mg/2,5 g injection.

Dopamine antagonists

Concomitant treatment with dopamine antagonists such as metoclopramide may result in diminution of the effects of both medicines on the gastrointestinal tract.

Beta-adrenergic agents

The tachycardic effects of beta-adrenergic agents may be enhanced by BUSCOPAN COMPOSITUM 20 mg/2,5 g injection.

Alcohol

The effect of alcohol and BUSCOPAN COMPOSITUM 20 mg/2,5 g injection can be potentiated when taken concurrently.

Additional interactions of pyrazolones

Pyrazolones may also cause interactions with oral anticoagulants, captopril, lithium and triamterene. The efficacy of antihypertensives and diuretics may be affected by pyrazolones. It is not known to what extent metamizole causes these interactions

BUSCOPAN COMPOSITUM 20 mg/2,5 g injection may also alter the effect of other active substances such as digoxin.

4.6 Fertility, pregnancy and lactation

Pregnancy and Breastfeeding

Hyoscine butylbromide:

Safety during pregnancy and lactation has not been established.

Metamizole sodium monohydrate:

Metamizole sodium monohydrate passes the placental barrier and is excreted in breast milk and should therefore only be used during pregnancy and lactation after careful consideration of the indications.

The breakdown products of metamizole are excreted into breast milk in considerable amounts and a risk to the breastfed infant cannot be excluded. Especially the repeated use of metamizole during breastfeeding must therefore be avoided. In case of a single administration of metamizole mothers are advised to collect and discard the breastmilk for 48 hours from its administration.

Fertility

No studies on the effects on human fertility have been conducted.

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. Patients should be advised that they may experience undesirable effects such as accommodation disturbances and dizziness during parenteral treatment with hyoscine butylbromide. If taken in the recommended dose, metamizole is not expected to affect concentration or reactions. As a precaution, at least if higher doses are taken, the possibility of impaired reactions should be borne in mind, and patients should be advised not to drive, operate machinery or conduct hazardous activities. This applies in particular in combination with alcohol.

4.8 Undesirable effects

Hyoscine butylbromide:

Side-effects of antimuscarinic agents include dryness of the mouth with difficulty of swallowing and talking, thirst, dilation of the pupils (mydriasis) with loss of accommodation (cycloplegia) and photophobia, flushing and dryness of the skin, transient bradycardia followed by tachycardia, with palpitation and arrhythmias, and urinary urgency, difficulty and retention, as well as reduction in the tone and mobility of the gastro-intestinal tract leading to constipation. Occasionally vomiting, giddiness and staggering may occur. Retrosternal pain may occur due to increased gastric reflux. Tricyclic anti-depressants, quinidine and amantadine can potentiate the anticholinergic effect of hyoscine butylbromide. Hyoscine butylbromide does not readily cross the blood-brain barrier, so central effects are rare.

Hyoscine butylbromide may cause drowsiness; patients so affected should not drive or operate machinery. Patients should abstain from alcohol.

Metamizole:

Severe anaphylactic reaction may occur. Other signs of allergy which can affect the skin, mucosa, the granulopoetic system (leucopoenia, agranulocytosis) or the circulation (shock) may also occur. Very serious or even life-threatening bullous skin reactions, generally with mucous membrane involvement (Stevens-Johnson Syndrome, Lyell Syndrome), have been reported with medications containing metamizole. Should such a reaction occur, BUSCOPAN COMPOSITUM 20 mg / 2,5 g injection should be discontinued at once and a physician immediately consulted.

Patients suffering from existing disturbances of blood cell formation (e.g. under cytostatic treatment) should only use BUSCOPAN COMPOSITUM under medical supervision.
Particular care is required in patients with systolic blood pressure values below 100 mm Hg in patients with unstable circulation (myocardial infarction, multiple injuries, initial shock).
Should symptoms of agranulocytosis, such as high fever, chills, sore throat, difficulty in swallowing, inflammation in the mouth, nose and throat as well as in the genital or anal region, occur during treatment, it should be discontinued immediately and the doctor concerned informed at once.
Shock may occur immediately or up to 1 hour after administration. If anaphylactic shock should occur intensive treatment for shock should be commenced without delay. In parenteral administration the injection should be stopped immediately at the first sign of shock; the cannula should be left in the vein or access to the vein should be sought; the patient should be laid on his side and the respiratory passages kept free of obstruction.
Counter-measures: administration of adrenaline, monitoring of pulse rate and blood pressure (attention : dysrhythmia!); anti-histamine agents; glucocorticoids (e.g. prednisolone up to 1 g i.v.); administration of plasma volume expanders; artificial respiration.]

Frequency of undesirable effects is classified according to MedDRA system:

Very common ≥ 1/10

Common ≥ 1/100, < 1/10

Uncommon ≥ 1/1000, < 1/100

Rare ≥ 1/10 000, < 1/1000

Very rare < 1/10 000, including isolated reports

Not known (cannot be estimated from available data)

Blood and lymphatic system disorders

Uncommon: leukopenia, agranulocytosis (including fatal cases)

Very rare: thrombocytopenia

Not known: sepsis (including fatal cases), aplastic anaemia, pancytopenia (including fatal cases). These are presumably immunological reactions. They can occur even if BUSCOPAN COMPOSITUM 20 mg/2,5 g injection was administered on previous occasions without complications.

There are signs to suggest that the risk of agranulocytosis may be elevated if BUSCOPAN COMPOSITUM 20 mg/2,5 g injection is used for more than one week. Agranulocytosis is manifest in the form of pyrexia, chills, oropharyngeal pain, dysphagia, stomatitis, rhinitis, pharyngitis, genital tract inflammation, and anal inflammation. These signs may be minimal in patients on antibiotics. There is little or no lymphadenopathy or splenomegaly. The red blood cell sedimentation rate is markedly increased; the granulocytes are considerably reduced or absent altogether.

Haemoglobin, red blood cell count and platelet counts may be abnormal.

It is strongly recommended that BUSCOPAN COMPOSITUM 20 mg/2,5 g injection be discontinued immediately and a doctor be consulted, and not only when the lab test results are available, if there is an unexpected deterioration in the patient's general condition, the fever does not subside or reappears, or if there are painful changes in the mucosa of the mouth, nose and throat.

Immune system disorders, skin and subcutaneous tissue disorders

Uncommon: drug eruption, skin reactions.

Rare: anaphylactic reaction, anaphylactoid reaction (especially after parenteral administration), asthma in patients with analgesic asthma syndrome, rash maculo-papular

Very rare: toxic epidermal necrolysis, Stevens-Johnson syndrome

Not known: anaphylactic shock including fatal outcome, dyspnoea; hypersensitivity; sweating abnormal

Milder reactions (e.g. skin and mucosal reactions, such as pruritus, burning sensation, erythema, swelling, as well as dyspnoea and gastro-intestinal disorders) may lead on to more severe reactions (e.g. generalised urticaria, severe angioedema including the laryngeal region, severe

bronchospasm, arrhythmia, decreased blood pressure with sometimes initially increased blood pressure). BUSCOPAN COMPOSITUM 20 mg/2,5 g injection must therefore be discontinued immediately if skin reactions occur. In case of severe skin reactions, a physician should immediately be consulted.

Anaphylactic reactions can develop during or immediately after injection, but can also develop some hours later. Reactions generally occur, however, within the first hour of administration. Appropriate tr*eatment should be started as soon as signs/symptoms of anaphylaxis appear.*

Eye disorders

Uncommon: accommodation disorders

Not known: mydriasis; increased intraocular pressure

Cardiac disorders

Not known: tachycardia, Kounis Syndrome

Vascular disorders

Common: hypotension, dizziness

Uncommon: shock, injection site pain; flushing

Very rare: phlebitis

Not known: injection site reaction

Hypotensive reactions occurring during or after use may be medicine-induced, and do not go hand in hand with other signs of anaphylactoid and/or anaphylactic reactions. Such a reaction can lead to a severe fall in blood pressure. Rapid intravenous injection increases the risk of hypotensive reactions.

In case of hyperpyrexia, or after a too rapid injection, there may be a dose-dependent and critical drop in blood pressure with no other signs of medicine intolerance.

Gastrointestinal disorders

Common: dry mouth

Not known: gastrointestinal haemorrhage

Renal and urinary disorders:

Very rare: acute renal failure, anuria; interstitial nephritis, oliguria, proteinuria, renal impairment

Not known: urinary retention, chromaturia

Excretion of rubazonic acid, a harmless metabolite of metamizole, may cause a red colouration of the urine, which disappears on discontinuation of treatment.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of BUSCOPAN COMPOSITUM is important. It allows continued monitoring of the benefit/risk balance of BUSCOPAN COMPOSITUM. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8, or to the Pharmacovigilance Unit at CFAO at chcsa-za-safety@cfao.com.

4.9 Overdose

Symptoms:

Hyoscine butylbromide:

In the case of overdose, anticholinergic effects may be observed.

Toxic doses cause tachycardia, rapid respiration, hyperpyrexia and central nervous system stimulation marked by restlessness, confusion and, excitement, paranoid and psychotic reactions, hallucinations and delirium, and occasionally seizures or convulsions. A rash may appear on the face and upper trunk.

After very high doses, elimination of the metabolic rubazonic acid can cause reddish discolouration of the urine.

Metamizole:

Acute overdosage or chronic use in excessive dosage lead to dizziness, nausea, emesis, gastro-intestinal pains, state of agitation, convulsion, clonic cramp, shock, coma, respiratory paralysis,

liver and renal damage, sodium and fluid retention with pulmonary oedema in cardiac patients, risk of allergy and anaphylactic reactions, leucopoenia, thrombocytopenia, agranulocytosis and aplastic anaemia.]

Therapy:

Hyoscine butylbromide:

Treat spastic conditions first - diazepam 10 - 20 mg i.v./i.m. Symptoms of BUSCOPAN COMPOSITUM overdosage respond to parasympathomimetics. In patients with glaucoma, pilocarpine should be used locally.

Further treatment: Symptomatic and supportive.

If required, parasympathomimetic medicines should be administered.

Opthalmological 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 or artificial respiration should be considered. Catheterisation may be required for urinary retention. In addition, appropriate supportive measures should be used as required.

Metamizole:

There is no known specific antidote for metamizole. If metamizole was administered only recently, absorption-reducing measures (e.g. activated charcoal) can be administered in an effort to limit absorption by the body. The major metabolite (4-N-methyl-amino-antipyrine) can be eliminated by means of haemodialysis, haemofiltration, haemoperfusion or plasma filtration. Treatment of intoxication and prevention of severe complications may require general and specific intensive medical monitoring and treatment.

Acute measures in the event of severe medicine intolerance (shock):

At the first signs (e.g. skin reactions such as urticaria and flushing, restlessness, headache, profuse sweating, nausea) stop the administration immediately.

Leave the cannula in the vein or set up a venous access. In addition to the usual emergency measures such as tilting the head and upper body back, maintaining the airways, administering oxygen, it may be necessary to administer sympathomimetics, volume expanders or glucocorticoids.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 11.2 Gastro-intestinal antispasmodics and cholinolytics (anticholinergic)

BUSCOPAN COMPOSITUM 20 mg/2,5 g injection has a selective antispasmodic action on the smooth muscle of the gastro-intestinal, biliary and genito-urinary tracts. It also has analgesic properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection

Tartaric acid

6.2 Incompatibilities

BUSCOPAN COMPOSITUM 20 mg/2,5 g injection should not be added to pH correcting intravenous solutions of high volume or parenteral nutrition (amino acids, lipids).

Because of the possibility of incompatibilities, BUSCOPAN COMPOSITUM 20 mg/2,5 g injection must not be mixed with other drugs in the same syringe (see section 4.2).

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 °C. [Keep out of reach of children.]

6.5 Nature and contents of container

Ampoules of 5 ml in boxes of three ampoules.

6.6 Special precautions for disposal and other handling

No special requirements.

7. 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

8. REGISTRATION NUMBER

E/11.2/504

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 March 1994

10. DATE OF REVISION OF THE TEXT

03 February 2021

NAMIBIA Reg. No. 14/10.1/0198	NS1

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

BUSCOPAN® COMPOSITUM 20 mg/2,5 g

Injection

Hyoscine butylbromide and Metamizole sodium monohydrate

Read all of this leaflet carefully before you are given 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.

What is in this leaflet

1. What BUSCOPAN COMPOSITUM is and what it is used for
2. What you need to know before you use BUSCOPAN COMPOSITUM
3. How to use 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 20 mg/2,5 g injection is 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 use BUSCOPAN COMPOSITUM

BUSCOPAN COMPOSITUM should not be administered to you:

- 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 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 hemoglobin)
- 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 are in the last three months of pregnancy (see section “Pregnancy, breastfeeding and fertility”)
- if you suffer from myasthenia gravis (a chronic disease characterized by varying degrees of muscle weakness)
- If you suffer from granulocytopenia (a lack of white blood cells)
- If you have asthma
- if you have low blood pressure or circulation problems
- if you are being treated with medicines intended to treat coagulation problems and used intramuscularly (BUSCOPAN COMPOSITUM 20 mg/2,5 g injection can be given intravenously)
- Subcutaneous (under the skin) injection and intra-arterial (into an artery) injection

Warnings and precautions

Take special care with BUSCOPAN COMPOSITUM 20 mg/2,5 g injection:

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).

- If you suffer or have suffered from heart problems

Children and adolescents

It is not indicated for use in children and adolescents.

It is not indicated for use in children under 12 months of age.

Other medicines and BUSCOPAN COMPOSITUM 20 mg/2,5 g injection

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 cardiac arrhythmias (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 in people who are taking bupropion (a medicine used to treat depression and/or to help people stop smoking), as metamizole can lower blood levels of bupropion.

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

Using 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.

BUSCOPAN COMPOSITUM should not be used 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.

BUSCOPAN COMPOSITUM contain sugar and lactose

3. HOW TO USE BUSCOPAN COMPOSITUM

Your doctor will decide on the appropriate dosage for you.

BUSCOPAN COMPOSITUM 20 mg/2,5 g is given by injection.

You will not be expected to give yourself BUSCOPAN COMPOSITUM 20 mg/2,5 g injection. It will be given to you by a person who is qualified to do so.

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 being given BUSCOPAN COMPOSITUM.

If you get more BUSCOPAN COMPOSITUM than you should:

Since a health care provider will administer BUSCOPAN COMPOSITUM 20 mg/2,5 g injection, he / she will control the dosage. However, in the event of overdosage, your doctor will take appropriate actions.

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 use BUSCOPAN COMPOSITUM

Since a health care provider will administer BUSCOPAN COMPOSITUM, it is unlikely that the dose will be missed.

4. Possible side effects

BUSCOPAN COMPOSITUM can have side effects.

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.
- 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.
- Rashes, swelling, blisters or sores on the skin, mouth, lips, nose or genitals, or peeling skin.
- Difficulty swallowing.
- Increased heart rate or other changes to your heart rate or rhythm.
- Vomiting blood or blood in the bowel movements.

These are all very serious side effects. You may need urgent medical attention or hospitalisation. Milder reactions may lead to more severe reactions so you should stop taking BUSCOPAN COMPOSITUM and contact your doctor immediately if you experience any of the above.

- 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.

Other side-effects that normally do not need medical treatment:

- Flushing

- Pain or irritation at the site where the injection was given
- Dry mouth.
- Red discoloration of the urine. This usually disappears when treatment is stopped.

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:

- The Pharmacovigilance Unit at chcsa-za-safety@cfao.com or
- SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

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 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).

6. Contents of the pack and other information

What BUSCOPAN COMPOSITUM contain:

The active substances are hyoscine butylbromide and metamizole sodium monohydrate.

Each 5 ml of solution contains 20 mg of hyoscine butylbromide and 2,5 g of metamizole sodium monohydrate.

The other ingredients are water for injection and tartaric acid.

What BUSCOPAN COMPOSITUM looks like and contents of the pack:

A clear, slightly yellowish solution.

Amber glass ampoules of 5 ml in boxes of three ampoules.

Holder of Certificate of Registration:

CFAO Healthcare South Africa (Pty) Ltd

Atrium op 5de, 6de Vloer, Sandton City

Corner Maude & 5th Straat

Sandton, Gauteng

2146

This leaflet was last revised in

03 February 2021

Registration number

E/11.2/502

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS

S4

BUSCOPAN® COMPOSITUM 20 mg/2,5 g

Inspuiting

Hiosienbutielbromied en metamisool natrium monohidraat

Lees hierdie hele inligtingsblad noulettend deur voordat BUSCOPAN COMPOSITUM aan jou toegedien word.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad

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

3. Wat is BUSCOPAN COMPOSITUM en waarvoor word dit gebruik

Hiosienbutielbromied behoort aan ’n groep van medisyne genaamd antispasmodiese middels (medisyne wat krampende spiere in die maag en derms laat ontspan). metamisool natrium

monohidraat is ’n pynstillende middel (medisyne wat pyn verlig).

BUSCOPAN COMPOSITUM 20 mg/2,5 g inspuiting word gebruik in die behandeling van akute, hewige pyn of spasmas van byvoorbeeld die biliêre weg (galblaas en galbuise) en die urienweg.

4. Wat jy moet weet voordat jy BUSCOPAN COMPOSITUM gebruik

BUSCOPAN COMPOSITUM moenie aan jou toegedien word 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 in afdeling 6)
- indien jy voorheen nadat jy enige van hierdie middels gebruik het, ’n afname in die aantal witbloedselle (agranulositose) ervaar het
- indien jy simptome van asma, rinitis (loopneus of toe neus) of urtikarie (rooierige kolle of korwe op die vel, wat mag jeuk) gehad het nadat jy aspirien, parasetamol of nie-steroïdale anti-inflammatoriese middels geneem het, aangesien kruissensitiwiteit kan voorkom
- indien jy verswakte beenmurgfunksie gehad het, byvoorbeeld nadat jy chemoterapie ontvang het, of indien jy bloedsiektes gehad het
- indien jy ’n gebrek aan glukose-6-fosfaat-dehidrogenase het weens ’n genetiese afwyking
- 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 gevolglik sukkel om te urineer
- indien daar ’n vernouing in jou spysverteringskanaal is
- indien jy aan verlammende of obstruktiewe ileus (dermverlamming) ly
- indien jou hartspoed vinnig is (tagikardie)
- indien jy megakolon het (abnormaal groot dikderm)
- indien jy in die laaste drie maande van jou swangerskap is (sien die afdeling “Swangerskap, borsvoeding en vrugbaarheid”)

- indien jy aan miastenie gravis ly (’n chroniese siekte wat deur wisselende grade van spierswakheid gekenmerk word)
- indien jy aan granulositopenie ly (’n tekort aan witbloedselle)
- indien jy asma het
- indien jy lae bloeddruk of probleme met jou bloedsomloop het
- indien jy met medisyne vir stollingsprobleme behandel word en dit binnespiers gebruik word (BUSCOPAN COMPOSITUM 20 mg/2,5 g inspuiting kan binneaars gegee word)
- subkutane inspuiting (onder die vel) en intra-arteriële inspuiting (in ’n slagaar).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met BUSCOPAN COMPOSITUM 20 mg/2,5 g inspuiting:

Konsulteer dadelik jou dokter, apteker of ander gesondheidsorgverskaffer:

- Indien hewige abdominale pyn (buikpyn) waarvan die oorsprong onbekend is aanhou of vererger, of voorkom saam met simptome soos koors, naarheid, braking, 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 mag dui op agranulositose (afname in witbloedselle), 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, volgehoue 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 dui op anafilakse/anafilaktiese skok (duiseligheid, kortasemheid, rinitis, swelling van die gesig (angioneurotiese edeem), val in bloeddruk,

rooierige kolle op die vel wat skielik verskyn). 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 sirkulasie 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 jou maag of ingewande gebloei het, aangesien dit gerapporteer is by pasiënte wat met metamisool behandel 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 dan aan ongediagnoseerde nouhoek-gloukoom mag ly (’n siekte wat verhoogde druk binne in die oë veroorsaak).
- Indien jy aan hartprobleme ly of gely het.

Kinders en adolessente

Dit word nie aangedui vir gebruik by kinders en adolessente nie.

Dit word nie aangedui vir gebruik by kinders onder die ouderdom van 12 maande nie.

Ander medisyne en BUSCOPAN COMPOSITUM 20 mg/2,5 g inspuiting

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

Gepaardgaande gebruik van BUSCOPAN COMPOSITUM mag die anticholinergiese effek (soos droë mond, hardlywigheid) versterk van medisyne vir die behandeling van depressie (trisikliese en tetrasikliese antidepressante), medisyne vir die behandeling van allergieë (antihistamiene), medisyne vir die behandeling van party geestesteurings (antipsigotika), medisyne vir die behandeling van hartaritmieë (kinidien, disopiramied), medisyne vir die behandeling van virusinfeksies en/of behandeling van Parkinson se siekte (amantadien) en ander anticholinergiese medisyne (byvoorbeeld tiotropium, ipratropium en atropien-tipe verbindings).
Indien dit saam met dopamienantagoniste geneem word (soos metoklopramied, gebruik om braking, naarheid en/of verlamming van maagbewegings te behandel) mag dit die effek van beide medisynes verswak.

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

Indien dit gepaardgaande met siklosporien geneem word (’n medisyne wat die immuunreaksies van die liggaam verminder), kan die bloedvlakke van siklosporien verlaag word en moet dus gereeld gemeet 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 vorm in die bloed nie (orale antikoagulante), medisyne vir die behandeling van hoë bloeddruk, diuretika (kaptopriel, triamtereen) en medisyne vir die behandeling van geestesteurings (litium).

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

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

BUSCOPAN COMPOSITUM moet versigtig gebruik word by pasiënte wat laedosis-aspirien (vir hartbeskerming) neem, aangesien metamisool die antiplaatjie-effek van aspirien mag verminder.

BUSCOPAN COMPOSITUM moet met omsigtigheid gebruik word by mense wat bupropioon (’n medisyne wat gebruik word om depressie te behandel en/of om mense te help om op te hou rook) neem, aangesien metamisool die bloedvlakke van bupropioon kan verlaag.

By diabete mag metamisool sommige van die toetse om bloedsuikervlakke te beheer affekteer (glukose-oksidasetoets).

Gebruik van BUSCOPAN COMPOSITUM saam met alkohol

Die effekte van 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 ander gesondheidsorgverskaffer voordat jy hierdie medisynegebruik.

BUSCOPAN COMPOSITUM moenie gebruik word indien jy in die laaste 3 maande van jou swangerskap is nie.

Bestuur en die gebruik van masjiene

Visie versteurings en duiseligheid mag tydens behandeling voorkom. Dit moet ook in ag geneem word dat konsentrasie en reaksietye teen hoër konsentrasies geaffekteer mag word, dus moet

voertuigbestuur, hantering van masjinerie en ander gevaarlike aktiwiteite vermy word. Dit geld veral wanneer jy alkohol ingeneem het.

BUSCOPAN COMPOSITUM bevat suiker en laktose.

3. HOE OM BUSCOPAN COMPOSITUM TE GEBRUIK

Jou dokter sal besluit watter dosis geskik is vir jou.
BUSCOPAN COMPOSITUM 20 mg/2,5 g word deur middel van ’n inspuiting toegedien.
Daar sal nie van jou verwag word om BUSCOPAN COMPOSITUM 20 mg/2,5 g inspuiting self te gebruik nie. Dit sal deur ’n gekwalifiseerde persoon aan jou toegedien word.

Dit mag nodig wees dat die dosering verlaag word indien jy bejaard 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 BUSCOPAN COMPOSITUM vir jou gegee word.

Indien jy meer BUSCOPAN COMPOSITUM ontvang as wat jy moet:
Aangesien ’n gesondheidsorgverskaffer BUSCOPAN COMPOSITUM 20 mg/2,5 g inspuiting sal toedien, sal hy/sy die dosering kontroleer. Indien oordosering egter voorkom, sal jou dokter die nodige doen om dit te behandel.

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 visie versteurings mag voorkom.

Naarheid, braking, buikpyn, agteruitgang van nierfunksie kan voorkom, en by seldsame geleenthede 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 mag die urine rooi verkleur, wat weer verdwyn wanneer behandeling gestaak word.

Indien jy vergeet om BUSCOPAN COMPOSITUM te gebruik

Aangesien ’n gesondheidsorgverskaffer BUSCOPAN COMPOSITUM sal toedien, is dit onwaarskynlik dat ’n dosis oorgeslaan sal word.

4. Moontlike newe-effekte

BUSCOPAN COMPOSITUM kan newe-effekte hê.

Indien enige van die volgende gebeur, hou op om BUSCOPAN COMPOSITUM te gebruik en sê onmiddellik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal. Jy mag dringende 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 mag sukkel om te sluk of asem te haal en jou bewussyn verloor.
- Sukkel om asem te haal, voel flou of duiselig.
- Allergiese en hipersensitiwiteitsreaksies – die tekens mag veluitslag en gejeuk, gehyg en kortasemheid insluit.
- 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.
- Uitslag, swelling, blase of sere op die vel, mond, lippe, neus of geslagsdele, of vel wat afskilfer.

- Sukkel om te sluk.
- Versnelde harttempo of ander veranderings aan jou hartspoed of -ritme.
- Braak bloed, of bloed in die stoelgang.

Hierdie is baie ernstige newe-effekte. Jy mag dringende mediese bystand of hospitalisasie benodig. Geringe reaksies mag vererger tot hewige reaksies, dus moet jy ophou om BUSCOPAN COMPOSITUM te neem en jou dokter onmiddellik kontak indien jy enige van bogenoemde ondervind.

- Indien jy pynlike, rooi oë met verlies aan visie ervaar nadat jy BUSCOPAN COMPOSITUM gebruik het, hou op om dit te ontvang en sê onmiddellik vir jou dokter. Jy mag ’n oogprobleem genaamd gloukoom hê en dringende mediese sorg benodig.

Ander newe-effekte wat normaalweg nie mediese behandeling benodig nie:

- Blosing.
- Pyn of irritasie by die plek waar die inspuiting toegedien is.
- Droë mond.
- Rooi verkleuring van die urine. Dit klaar gewoonlik op wanneer behandeling gestaak word.

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

Rapportering van newe-effekte:

Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte rapporteer aan:

- Die Farmakologiese waaksaamheid afdeling by CFAO: chcsa-za-safety@cfao.com, of
- SAHPRA via die vorm om ongunstige geneesmiddelreaksies te rapporteer, wat aanlyn by SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8.

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

5. Hoe om BUSCOPAN COMPOSITUM te bêre

Bêre alle medisyne buite bereik van kinders.

Bêre by of onder 30 °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.

6. Inhoud van die pak en ander inligting

Wat BUSCOPAN COMPOSITUM bevat:

Die aktiewe bestanddele is hiosienbutielbromied en metamisool natrium monohidraat.

Elke 5 ml van die oplossing bevat 20 mg hiosienbutielbromied en 2,5 g metamisool natrium monohidraat.

Die ander bestanddele is water vir inspuiting en wynsteensuur.

Hoe BUSCOPAN COMPOSITUM lyk en inhoud van die verpakking:

'n Deurskynende, effens gelerige oplossing.

5 ml amber glasampul in kartonhouers wat drie ampulle bevat.

Houer van die Registrasiesertifikaat:

CFAO Healthcare South Africa (Pty) Ltd

Atrium op 5de, 6de Floor, Sandton City

Corner Maude & 5th Street

Sandton, Gauteng

2146

Hierdie inligtingsblad is laas hersien

03 Februarie 2021

Registrasienommer

E/11.2/502