Approved Patient Information Leaflet

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

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 Sanofi: za.drugsafety@sanofi.com (email) or 011 256-3700 (tel), 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 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:

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