PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SCOPEX CO TABLETS 10 mg / 250 mg tablets

Hyoscine-N-butylbromide, metamizole sodium

Contains sugar (sucrose): 82,52 mg

Read all of this leaflet carefully before you start taking SCOPEX CO TABLETS

- 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.

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

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

SCOPEX CO TABLETS, is one of a group of medicines called Cholinolytics (anticholinergics) affecting autonomic functions.

SCOPEX CO TABLETS is a combination of hyoscine-N-butylbromide with metamizole sodium used to relieve spasm of the smooth muscle in the gastrointestinal tract, the biliary tract and the urogenital tract, where a pain stiller as well as an antispasmodic effect is required.

SCOPEX CO TABLETS is indicated for gallstones or urinary stones, associated with sudden abdominal pain (colic), sudden severe abdominal pain, cramping pain in the lower abdomen before or during a period (dysmenorrhoea), and painful spastic contractions of the uterus (female genital system).

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

Do not take SCOPEX CO TABLETS

- if you are allergic (hypersensitive) to pyrazolone or pyrazolidines (eg metamizole sodium, isopropylaminophenazone, propiphenazone, phenazone or phenylbutazone)hyoscine-N-butylbromide, metamizole sodium or any of the other ingredients of SCOPEX CO TABLETS (listed in section 6),
- if the number of white blood cells in the blood (agranulocytosis) have severely decreased after using any of these substances,
- if you suffer from eye conditions such as increased pressure in the eye (glaucoma),
- 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 your average body temperature is high, especially children,
- if you suffer from increased heart rate (tachycardia),
- if you have low blood pressure, heart problems or history of heart problems, or increased blood pressure,
- if you have experienced a severe allergic reaction series of symptoms, including a rash, low pulse, and shock (anaphylaxis),
- if you suffer from granulocytopenia (a lack of white blood cells),
- if you have asthma, or have previously reacted to painkillers (such as salicylates, paracetamol, diclofenac, ibuprofen, indomethacin or naproxen),
- if you think you may have reacted to any other NSAID (e.g. aspirin, ibuprofen) with sensitivity reactions like asthma, acute rhinitis (runny nose) and urticaria (itchy skin rash),
- 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 have megacolon (abnormally large colon),
- if you suffer from myasthenia gravis (a chronic disease characterized by varying degrees of muscle weakness),
- if you have asthma,
- if you are in the last three months of pregnancy (see section 2).

Warnings and precautions

Special care should be taken with SCOPEX CO TABLETS if:

- you suffer from increased heart rate (tachycardia), have heart problems or any pre-existing heart problems, or increased blood pressure,
- you experience 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,
- you use SCOPEX CO TABLETS over a prolonged period, you can develop a condition of lowered white blood cell count (see section 4), which can develop to be severe and dangerous,
- 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. In these cases, you should stop the treatment and consult your doctor immediately,
- if you have 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,

- 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,
- you suffer from asthma syndrome due to painkillers or intolerance to painkillers, intolerance to alcohol, as the risk of possible serious allergic reactions is greater. Patients should not drink alcohol if this is the case,
- if you have long-term rash problems on the skin (chronic urticaria),
- if you have asthma or allergies, the probability of developing anaphylactic shock is higher,
- if you have had an anaphylactic or immunological reaction (such as agranulocytosis) to SCOPEX CO TABLETS, you are also at high risk of reacting in a similar way to other pyrazolones and pyrazolidines,
- in the event of lesions on the skin or mucous membranes, discontinue treatment with this medicine and consult your doctor immediately,
- if you have had bleeding from the stomach or intestines since this has been reported in patients treated with metamizole sodium,
- if after using SCOPEX CO TABLETS 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),
- you are an elderly man or you have fever,
- if you suffer from decreased kidney or liver function or if you are an elderly patient,
- if you are an diabetic patient, your blood sugar results can be affected.

Liver problems

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 SCOPEX CO TABLETS and contact a doctor if you have symptoms of liver problems such as feeling sick (nausea or vomiting), fever, feeling tired, loss of appetite, dark-coloured

urine, light-coloured bowel movements, yellowing of the skin or white part of the eyes, itching, rash or upper stomach pain. Your doctor will check the functioning of your liver.

You should not take SCOPEX CO TABLETS if you have previously taken any metamizole-containing medicinal product and had liver problems.

SCOPEX CO TABLETS contains sucrose (a common sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking SCOPEX CO TABLETS.

Children

Do not give SCOPEX CO TABLETS to small children as it is unlikely to be safe.

Other medicines and SCOPEX CO TABLETS

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

The concomitant use of:

- 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,
- if it is taken together with chlorpromazine (medicine to treat mental disorders) it can cause a drop in body temperature,
- SCOPEX CO TABLETS should be used with caution in patients taking low-dose aspirin (as a cardiac protector), as metamizole sodium may decrease the antiplatelet effect of aspirin,
- SCOPEX CO TABLETS 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 sodium can lower blood levels of bupropion,
- amantadine (medication used to treat Parkinsons),
- antihistamines (medications used to treat allergies),

- butyrophenones or phenothiazines (medications used to treat psychiatric disorders),
- tricyclic antidepressants such as amitriptyline,
- other medication such as antiarrhythmic's (quinidine or disopyramide) or other drugs that block the action of the neurotransmitter, acetylcholine (anticholinergics e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified,
- 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,
- metamizole sodium can intensify the effects of beta-adrenergic medicines (e.g. salmeterol) by increasing heart rate and blood pressure (tachycardiac effects),
- the effects of alcohol and SCOPEX CO TABLETS can be enhanced if taken together,
- affect the effectiveness of oral anticoagulants (prevent the blood from clotting, antihypertensives (medicines that lower blood pressure) or diuretics (medicines that increase fluid elimination),
- metamizole sodium can interact with digoxin (medicines used to treat heart failure) or lithium (medicines for the treatment of mental disorders.

SCOPEX CO TABLETS with food

There are no special requirements concerning intake with or without food (see section 3).

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 SCOPEX CO TABLETS.

The use of SCOPEX CO TABLETS is not recommended and safety during pregnancy and breastfeeding has not been established.

No data on the influence of fertility is available.

Driving and using machines

SCOPEX CO TABLETS may cause drowsiness and dulling of mental alertness, which could have a moderate influence on the ability to perform or execute tasks.

It is not always possible to predict to what extent SCOPEX CO TABLETS may interfere with your daily actitivies. You should ensure that you express caution in activites requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which SCOPEX CO TABLETS affects you.

3. How to take SCOPEX CO TABLETS

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

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

SCOPEX CO TABLETS is for oral use only.

The maximum daily dose of SCOPEX CO TABLETS is 1 to 2 tablets taken three times a day until pain is relieved.

If you take more SCOPEX CO TABLETS than you should

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

Overdoses of hyoscine produce toxic effects similar to those of atropine including palpitations, dilated pupils, difficulty swallowing, hot dry skin, thirst, dizziness, hallucinations, restlessness, tremor, fatigue, disorientation and rash on face and upper body, but central stimulation rarely progresses to depression. The main central systems are increased drowsiness or a state of near-unconsciousness leading to coma. After the administration of very high doses, a red discoloration of the urine may occur, which disappears when treatment is stopped.

Overdoses of metamizole sodium cause nausea, vomiting, abdominal pain, deterioration of kidney and liver function, involuntary muscular contraction, significant lung weakness and shortness of breath or paralysis, and low blood cell counts.

Treatment is symptomatic and supportive as there is no known antidote. When needed, a class of pharmacological agents that activate the parasympathetic division of the autonomic nervous system (parasympathomimetic medicines) should be administered.

If you forget to take SCOPEX CO TABLETS

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

4. Possible side effects

SCOPEX CO TABLETS can have side effects.

Not all side effects reported for SCOPEX CO TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while SCOPEX CO TABLETS, please consult your health care provider for advice.

If any of the following happens, stop taking SCOPEX CO TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- difficulty in breathing, shortness of breath,
- development of skin rash and itching on face and upper trunk
- swelling of the hands, feet, ankles, face, lips and mouth or throat,
- chest pain or fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SCOPEX CO TABLETS. You may need urgent medical attention or hospitalisation.

Stop using SCOPEX CO TABLETS and immediately contact a doctor if you experience any of the following symptoms:

Feeling sick (nausea or vomiting), fever, feeling tired, loss of appetite, dark-coloured urine, light-coloured bowel movements, 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 section 2).

Tell your doctor if you notice any of the following:

Frequent side effects:

- Low blood pressure,
- diziiness.

Less frequent side effects:

- Skin rash, nausea, vomiting, difficulty breathing and shock (anaphylactic reaction),
- inability of the eyes to change focus,
- shock (sudden, rapid heartbeat, loss of consciousness),
- or flushing,
- dryness of the mouth,
- severe skin rash and itching, severe blistering,
- kidney failure or disorders,
- low urine output (oliguria).

Side effects with an unknown frequency:

- Life threatening allergic reaction and difficulty breathing,
- abnormal sweating,
- swelling, discomfort, severe pain of the throat, and difficulty swallowing and breathing,
- increased heart rate or other changes to your heart rate or rhythm,
- inability of the eyes to react to light and become fixed in the dilated position,

- sensitivity to bright lights,
- increased eye pressure,
- fast or irregular heart beat (palpitations and dysrhythmia),
- allergic, acute coronary syndrome (Kounis Syndrome),
- thirst,
- constipation,
- bleeding of the digestive tract,
- inflammation of the liver, yellowing of the skin and white part of eyes, increase in the blood level of liver enzymes, abnormal coloration of the urine,
- warmth and rapid reddening of your neck, upper chest, or face,
- dryness of the skin,
- itching or burning and unpleasant sensation on the skin,
- an outbreak of swollen, pale red bumps or plaques (wheals) on the skin that appear suddenly,
- problems emptying the bladder or no production or passing of urine,
- abnormal coloration of the urine.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to 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 SCOPEX CO TABLETS.

5. How to store SCOPEX CO TABLETS

Store all medicines out of reach of children.

- store at or below 30 °C,
- protect from light,

- keep the glass bottle tightly closed,
- do not use after the expiry date stated on the label / carton / bottle,
- do not dispose of unused medicine in drains or sewerage systems (e.g. toilets),
- return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What SCOPEX CO TABLETS contains

The active substance is hyoscine-N-butylbromide and metamizole sodium.

The other ingredients are:

Tablet core

Crospovidone, dibasic calcium phosphate (anhydrous), magnesium stearate, polvvinylpyrrolidone K25, purified talc.

Composition of Coating

Purified talc, syrup BP, subcoat suspension, tablet sealing solution, titanium syrup, wax solution

Tablet sealing solution

Acid stearic, hydroxypropylmethylcellulose (Methocel E5 premium), diethyl phthalate, polyvinlyl acetate phthalate, stearic acid, chloroform spirit, purified water

Subcoat suspension

akacia gum powder (low bioburden), calcium carbonate B.P., polyethylene glycol 6000, purified talc, titanium dioxide (CI 77891), syrup BP, chloroform spirit, nipastat.

Titanium syrup

Titanium dioxide (CI 77891), syrup B.P.

Syrup

Nipastat, sucrose (refined sugar), purified water, chloroform spirit

Wax solution

Carnauba wax, yellow beeswax, isopropyl alcohol.

Chloroform spirit

Chloroform, ethanol 96,5 %, purified water.

What SCOPEX CO TABLETS looks like and contents of the pack

Round and smooth, white sugar-coated tablets. Odourless.

Content of the packaging:

- SCOPEX CO TABLETS are packed in amber round glass bottles, with an extruded closed cell foam produced from low density polyethylene within a white polypropylene cap, containing either 100, 300 or 350 tablets and one or two silica gel(s) sachet(s).

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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