

Approved Patient Information Leaflet for BUSCOPAN® 10 mg tablets

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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BUSCOPAN® 10 mg tablets

Hyoscine butylbromide

Contains sugar: 41,2 mg sucrose per tablet.

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

BUSCOPAN 10 mg tablets are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use BUSCOPAN 10 mg tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What BUSCOPAN 10 mg tablets is and what it is used for
2. What you need to know before you use BUSCOPAN 10 mg tablets
3. How to use BUSCOPAN 10 mg tablets
4. Possible side effects
5. How to store BUSCOPAN 10 mg tablets
6. Contents of the pack and other information

1. What BUSCOPAN 10 mg tablets 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).

BUSCOPAN 10 mg tablets are used in the treatment of conditions associated with gastrointestinal spasm, that is, to relieve cramps in the muscles of the stomach and gut.

2. What you need to know before you take BUSCOPAN 10 mg tablets

Do not take BUSCOPAN 10 mg tablets:

- if you are hypersensitive (allergic) to hyoscine butylbromide or any of the other ingredients (listed in section 6)
- if you have myasthenia gravis (a very rare muscle weakness problem)
- if you have suspected or confirmed blockage of the bowel
- if you have a condition where the bowel is blocked and does not work properly (paralytic or obstructive ileus)
- if you have a very enlarged bowel (megacolon)
- If you have glaucoma (an eye problem with increased pressure in the eye)
- if you have porphyria (disturbances of metabolism that can be seen as disorders of the skin or other organs)
- if you have an enlarged prostate
- if you have a fever
- if you have tachycardia (fast heartbeat)
- if you have rare hereditary (inherited) conditions that may be incompatible with an ingredient in BUSCOPAN 10 mg tablets, namely sugar. Please refer to “**BUSCOPAN 10 mg tablets contain sugar**”.

Warnings and precautions

Take special care with BUSCOPAN 10 mg tablets:

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

- If you have severe, unexplained abdominal (belly) pain that persists or worsens or occurs

together with fever, nausea (feeling sick), vomiting, changes in your bowel movements, abdominal (belly) tenderness, low blood pressure, fainting or blood in your bowel movements.

Consult your doctor, pharmacist or other health care provider before taking BUSCOPAN 10 mg tablets:

- if you tend to have a very fast heart rate or other heart problems
- if you have a tendency to blockage problems of the gut or urinary tract or if you have difficulty or pain passing water (urine) such as men with prostate problems
- if you are prone to glaucoma (increased pressure in the eye)
- if you have been treated by a doctor for a severe sweating problem
- if you have a fever
- if you have abnormal liver or kidney function.

Other medicines and BUSCOPAN 10 mg tablets

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

BUSCOPAN 10 mg tablets can interfere with some other medicines, in particular:

- Antihistamines – used to treat hay fever and other allergies.
- Tricyclic or tetracyclic antidepressant medicines – used to treat depression.
- Quinidine or disopyramide – used to control your heartbeat.
- Amantadine – used for Parkinson's disease and flu.
- Antipsychotic medicines such as butyrophenones or phenothiazines – used to treat severe mental illness such as schizophrenia.
- Tiotropium, ipratropium or atropine-like medicines – medicines inhaled to treat breathing problems.
- Dopamine antagonists such as metoclopramide for feeling nauseous.
- Beta-adrenergic medicines such as salbutamol for asthma.

Pregnancy and breastfeeding

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 use BUSCOPAN 10 mg tablets if you are pregnant or breastfeeding your baby.

Driving and using machines

Some people may have temporary blurring of vision while taking BUSCOPAN 10 mg tablets. If this happens to you, wait until your vision returns to normal before driving or using any tools or machines.

BUSCOPAN 10 mg tablets contain sugar

One BUSCOPAN sugar-coated tablet contains 41,2 mg of sugar, equal to 411,8 mg of sugar per maximum recommended daily dose, which is 10 tablets. Patients with the rare hereditary condition of fructose intolerance should not take BUSCOPAN 10 mg tablets.

3. How to take BUSCOPAN 10 mg tablets

Always take BUSCOPAN 10 mg tablets exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- Adults and adolescents over 12 years of age: 1 – 2 tablets 3 to 4 times daily.
- Children 6 – 12 years of age: 1 tablet 3 times daily.

Swallow the tablets whole with enough liquid like water.

Do not crush or chew the tablets.

BUSCOPAN 10 mg tablets should not be taken on a continuous daily basis or for long periods

without investigating the cause of the pain. You must see a doctor if your symptoms worsen or do not improve after 3 days.

For infants and children under 6 years, BUSCOPAN 0,1 % syrup (containing 5 mg hyoscine butylbromide per 5 ml) is available.

If you take more BUSCOPAN 10 mg tablets than you should

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

If you forget to take BUSCOPAN 10 mg tablets

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 10 mg tablets may have side effects.

Not all side effects reported for BUSCOPAN 10 mg tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BUSCOPAN 10 mg tablets, please consult your health care provider for advice.

If any of the following happens, stop taking BUSCOPAN 10 mg tablets 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. The itchy rash may spread all over the body, as well as swelling. You may have difficulty in breathing and may lose consciousness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BUSCOPAN 10 mg tablets. You should seek urgent medical attention that may require hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you experience painful red eyes with loss of vision after taking BUSCOPAN 10 mg tablets, stop taking it and tell your doctor immediately. You may have an eye problem called glaucoma and should seek urgent medical attention.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Skin reactions such as hives, itching, rash or patchy red skin.
- Increased heart rate, slowing of the heart rate followed by increased heart rate with faster or irregular heartbeats, also called palpitations, and changes in the way the heart beats.
- Problems emptying the bladder.

Other side effects that do not normally need medical treatment:

- Dry mouth.
- Making less sweat than usual.
- Dryness of the skin.

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 10 mg tablets.

5. How to store BUSCOPAN 10 mg tablets

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 10 mg tablets contain

The active substance is hyoscine butylbromide.

Each tablet contains 10 mg of the active ingredient hyoscine butylbromide.

The other ingredients are dibasic calcium phosphate, maize starch, starch soluble, colloidal silica, tartaric acid, stearic acid, polyvidone, sucrose, talc, acacia, titanium dioxide, polyethylene glycol 6000, carnauba wax, beeswax white.

What BUSCOPAN 10 mg tablets look like and contents of the pack

White curved sugar-coated tablets.

Cartons containing blister packs of 10, 20 or 100 tablets.

Holder of certificate of registration

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