

Approved Patient Information Leaflet for BUSCOPAN 0,1 % syrup

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

BUSCOPAN® 0,1 % syrup

Hyoscine butylbromide

Sugar free.

Contains sweetener.

Contains 15 mg of saccharin sodium per 5 mL.

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

BUSCOPAN 0,1 % syrup is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use BUSCOPAN 0,1 % syrup 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 0,1 % syrup is and what it is used for
2. What you need to know before you use BUSCOPAN 0,1 % syrup
3. How to use BUSCOPAN 0,1 % syrup
4. Possible side effects
5. How to store BUSCOPAN 0,1 % syrup
6. Contents of the pack and other information

1. What BUSCOPAN 0,1 % syrup 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 0,1 % syrup is 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 0,1 % syrup

Do not take BUSCOPAN 0,1 % syrup

- 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).

Warnings and precautions

Take special care with BUSCOPAN 0,1 % syrup:

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 0,1 % syrup:

- 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 0,1 % syrup

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

BUSCOPAN 0,1 % syrup can interfere with some other medicines, in particular:

- Antihistamines – used to treat hayfever 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 if you are pregnant or breastfeeding your baby.

Driving and using machines

Some people may have temporary blurring of vision while taking BUSCOPAN 0,1 % syrup. If this happens to you, wait until your vision returns to normal before driving or using any tools or machines.

3. How to take BUSCOPAN 0,1 % syrup

Always take BUSCOPAN 0,1 % syrup 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:

Babies older than 1 month up to 3 months: 2,5 mL (half a medicine measure) three times daily.

Infants older than 3 months up to 1 year: 2,5 mL – 5 mL (half to 1 medicine measure) three times daily.

Children older than 1 year up to 3 years: 5 mL – 10 mL (1 to 2 medicine measures) three times daily.

Children older than 3 years up to 6 years: 10 mL (2 medicine measures) three times daily.

Children older than 6 years up to 12 years: 10 mL – 20 mL (2 to 4 medicine measures) three times daily.

Children older than 12 years and adults: 20 mL (4 medicine measures) four times daily.

The first dose must be the lowest recommended for age.

Do not take more than the maximum recommended dose for age.

BUSCOPAN 0,1 % syrup 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.

If you take more BUSCOPAN 0,1 % syrup 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 0,1 % syrup

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 0,1 % syrup may have side effects.

Not all side effects reported for BUSCOPAN 0,1 % syrup are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BUSCOPAN 0,1 % syrup, please consult your health care provider for advice.

If any of the following happens, stop taking BUSCOPAN 0,1 % syrup 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 0,1 % syrup. You may need urgent medical attention or hospitalisation.

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

- If you experience painful red eyes with loss of vision after taking BUSCOPAN 0,1 % syrup, stop

taking it and tell your doctor immediately. You may have an eye problem called glaucoma and need 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 0,1 % syrup.

5. How to store BUSCOPAN 0,1 % syrup

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BUSCOPAN 0,1 % syrup contains:

The active substance is hyoscine butylbromide.

Each 5 mL of syrup contains 5 mg of the active ingredient hyoscine butylbromide.

The solution is preserved with 0,08 % sorbic acid.

The other ingredients are: saccharin sodium, hydroxyethylcellulose, banana flavour and water purified.

What BUSCOPAN 0,1 % syrup looks like and contents of the pack:

A clear colourless to slightly yellow thick liquid with a banana odour.

Amber glass bottle of 100 mL with a white tamper-evident closure.

Holder of certificate of registration

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