

Buscopan®

10 mg tablets

(hyoscine butylbromide)

Package Leaflet: Information for the User

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What BUSCOPAN Tablets are and what they are used for
2. Before you take BUSCOPAN Tablets
3. How to take BUSCOPAN Tablets
4. Possible side effects
5. How to store BUSCOPAN Tablets
6. Further information

1. WHAT BUSCOPAN TABLETS ARE AND WHAT THEY ARE USED FOR

BUSCOPAN Tablets contain a medicine called “hyoscine butylbromide”. This belongs to a group of medicines called “antispasmodics”.

BUSCOPAN Tablets are used to relieve cramps in the muscles of your:

- Stomach
- Gut (intestine)
- Bladder and the tubes that lead to the outside of your body (urinary system)

It can also be used to relieve the symptoms of Irritable Bowel Syndrome (IBS).

2. BEFORE YOU TAKE BUSCOPAN TABLETS

Do not take BUSCOPAN Tablets if:

- You are allergic (hypersensitive) to hyoscine butylbromide or any of the other ingredients (listed in section 6)
- You have glaucoma (an eye problem)
- You have something called ‘myasthenia gravis’ (a very rare muscle weakness problem)
- You have a suspected or confirmed blockage of the bowel
- You have a condition where the bowel is blocked and does not work properly (paralytic or obstructive ileus). Symptoms include severe abdominal pain with lack of stools and/or nausea/vomiting
- You have a very enlarged bowel (megacolon)
- You are pregnant, likely to get pregnant, or are breast-feeding

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Take special care with BUSCOPAN Tablets

Check with your doctor or pharmacist before taking your medicine if:

- You have a very fast heart rate or other heart problems
- You have a problem with your thyroid gland such as an overactive thyroid gland
- You have difficulty or pain passing water (urine) such as men with prostate problems
- You have constipation
- You have a fever

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking BUSCOPAN Tablets.

Check with your doctor or pharmacist straight away if you have unexplained abdominal pain which persists or worsens or occurs with:

- fever
- feeling sick
- being sick
- changes in your bowel movements
- abdominal tenderness
- low blood pressure
- feeling faint or,
- blood in your bowel movements

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because BUSCOPAN Tablets can affect the way some other medicines work. Also some other medicines can affect the way BUSCOPAN Tablets work.

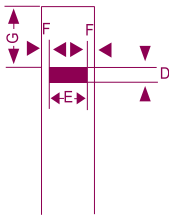
In particular, tell your doctor or pharmacist if you are taking any of the following:

- Medicines for depression called “tetracyclic antidepressants” or “tricyclic antidepressants” such as doxepin
- Medicines for allergies and travel sickness called “antihistamines”
- Medicines to control your heart beat such as quinidine or disopyramide
- Medicines for severe mental illness called ‘antipsychotics’ such as haloperidol or fluphenazine
- Medicines usually used for breathing problems such as tiotropium, ipratropium or atropine-like medicines
- Amantadine - for Parkinson's disease and flu
- Metoclopramide - for feeling sick (nausea)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking BUSCOPAN Tablets.

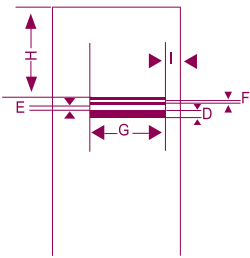
439050/GB/9

Technical Information
for pitch code



D = 2 mm
E = 5 mm
F = 1 mm
G = 80 mm

Technical Information
for control code



D = 1 mm
E = 0,65 mm
F = 0,35 mm
G = 10 mm
H = 35 mm
I = 2 mm

Additional Requirements of Packaging Site

Dimensions: mm 160 x 215,9 folded at 26 mm

pack2edit

Digital · Packaging · Development

Opella.

File information

GMID code:	652144 / 748461
Plant PM code:	10054721
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Market:	GB
Format:	160 x 215,9 mm
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Print colors:	Pan Black
Number of print colors:	1
Used font:	Arial / Praxis Com
Min. font size:	7,2 pt

Technical colors

Diecut-Legendcase

Free area

Glue points

Pregnancy and breast-feeding

Do not take BUSCOPAN Tablets if you are pregnant, likely to get pregnant or are breast-feeding.

Driving and using machines

Some people may have sight problems while taking this medicine. If this happens to you, wait until your sight returns to normal before driving or using any tools or machines.

Important information about some of the ingredients of BUSCOPAN Tablets

BUSCOPAN Tablets contain sucrose. Talk to your doctor before taking this medicine if they have told you that you cannot tolerate or digest some sugars.

3. HOW TO TAKE BUSCOPAN TABLETS

Always take your medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. BUSCOPAN Tablets should not be taken continuously for long periods of time.

Taking this medicine

- Take your tablets with water
- Do not break, crush or chew the tablets

How much to take

Adults and children over 12 years

- The usual dose is two tablets 4 times a day
- For Irritable Bowel Syndrome, your doctor may give you a lower starting dose of one tablet 3 times a day. This dose may be increased, if further relief is necessary

Children 6 - 12 years:

- The usual dose is one tablet 3 times a day

BUSCOPAN Tablets are not recommended for children under 6 years.

If you take more BUSCOPAN Tablets than you should

If you take more BUSCOPAN Tablets than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you even if there are no BUSCOPAN Tablets left.

If you forget to take BUSCOPAN Tablets

- If you forget a dose, take it as soon as you remember. However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, BUSCOPAN Tablets can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Stop taking your medicine and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

- Allergic reactions such as skin reactions e.g. nettle rash, itching (affects fewer than 1 in 100 people), rash, redness of the skin
- Severe allergic reactions (anaphylactic shock) such as difficulty breathing, feeling faint or dizzy (shock)
- Painful red eye with loss of vision

Other side effects

- Dry mouth (affects fewer than 1 in 100 people)
- Abnormal sweating or reduced sweating (affects fewer than 1 in 100 people)
- Increased heart rate (affects fewer than 1 in 100 people)
- Being unable to pass water (urine) (affects fewer than 1 in 1,000 people)

Reporting of side effects

If you get any 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 directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BUSCOPAN TABLETS

- Do not take this medicine after the expiry date which is printed on the packaging
- BUSCOPAN Tablets should be protected from light and stored in a dry place below 25°C
- Keep this medicine out of the sight and reach of children

6. FURTHER INFORMATION

What BUSCOPAN Tablets contain

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

The other ingredients are: calcium hydrogen phosphate, maize starch, soluble starch, colloidal silica, tartaric acid, stearic acid, sucrose, talc, acacia, titanium dioxide, macrogol 6000, carnauba wax, white beeswax and povidone.

What BUSCOPAN Tablets look like and contents of the pack

BUSCOPAN Tablets are sugar-coated, round and white in colour.

BUSCOPAN Tablets are available in blister packs of 56 and 100 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation is held by:
Opella
410 Thames Valley Park Drive
Reading
Berkshire
RG6 1PT
United Kingdom
Tel: 0800 035 2525
Email: uk-medicalinformation@sanofi.com

and the tablets are manufactured by:

Istituto De Angeli S.r.l.
Loc. Prulli, 103/C, 50066 Reggello (FI), Italy.

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