

sanofi

hyoscine butylbromide

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking BUSCOPAN CRAMPS, because it

contains important information for you to get the best results. • Keep this leaflet. You may need to use it again

- Ask your pharmacist if you need more information or advice
- You must contact a doctor if your symptoms worsen or do not improve after two weeks
- If a side effect occurs and gets troublesome, or seems serious to you, or if you experience a side effect not listed in this leaflet, please tell your pharmacist or doctor

- In this leaflet:

 1. What BUSCOPAN CRAMPS is and what it is used for
- 2. Before you take BUSCOPAN CRAMPS
 3. How to take BUSCOPAN CRAMPS
- 4. Possible side effects
- 5. How to store BUSCOPAN CRAMPS 6. Further information

1. WHAT BUSCOPAN CRAMPS IS AND WHAT IT IS USED FOR

- BUSCOPAN CRAMPS is a tablet containing hyoscine butylbromide. It belongs to a group of medicines called antispasmodics.
- It is used to relieve stomach and bowel cramps which cause pain and discomfort associated with your digestive tract, and in Irritable Bowel Syndrome.
- It may also be recommended by your doctor for spasm of the bladder and urinary tubes (urinary tract).
- It works by relaxing the cramping muscles of your stomach and bowel, or urinary tract.

What are abdominal cramps?

Abdominal cramps (or spasm) are due to the sudden, irregular tightening up of muscles in the wall of your stomach or bowel. While the precise cause is unknown, the muscles of the stomach and bowel appear to be very

- sensitive to things like: • Stress, eating and drinking habits
- Food allergies or intolerancesStimulants such as coffee
- Hormonal factors

Such things can trigger painful abdominal cramps or spasms if you have a sensitive digestive tract. You may also feel bloated, with excess wind and abdominal discomfort.

2. BEFORE YOU TAKE BUSCOPAN CRAMPS

Do not take BUSCOPAN CRAMPS if:

- You are allergic to hyoscine butylbromide or any of the other ingredients of BUSCOPAN CRAMPS (listed in Section 6)
- You are intolerant to or cannot digest some sugars (as the tablet coating contains a small amount of sucrose)
- 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 applies to you. If you are not sure, talk to your pharmacist or doctor before taking this

Take special care with BUSCOPAN CRAMPS

Check with your pharmacist or doctor before taking your medicine if any of the following apply to you:

- You are 40 years or over
- You have recently passed blood from the
- bowel
- You have severe constipation You are feeling sick or vomiting
- You have lost your appetite or lost weight
- You are looking pale and feeling tired
- You have difficulty or pain passing water (urine)
- You have a fever
- · You have abnormal vaginal bleeding or discharge
- You have recently travelled abroad (in case
- you have picked up a stomach bug) You have a very fast heart rate or other
- heart problems
- You have been treated by a doctor for a

severe sweating problem If you are not sure if any of the above applies to you, talk to your pharmacist or doctor before taking this medicine.

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

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

Taking other medicines Please tell your pharmacist or doctor if you

are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because BUSCOPAN CRAMPS can affect the way some other medicines work. Also some other medic can affect the way BUSCOPAN CRAMPS works.

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

- Antihistamines used to treat hay fever and other allergies
- Tetracyclic or tricyclic medicines used to
- treat depression and some types of pain
- Antipsychotic medicines such as butyrophenones or phenothiazines - used to treat severe mental illness such as schizophrenia
- Dopamine antagonists such as metoclopramide for feeling sick
- Beta 2 adrenergic medicines such as
- salbutamol inhalers for asthma Quinidine or disopyramide - used to control
- your heart beat • Amantadine - used for Parkinson's disease
- and flu Anticholinergic medicines such as
- tiotropium, ipratropium or atropine-like medicines - usually inhaled to treat breathing problems If you are not sure if any of the above applies

to you, talk to your pharmacist or doctor before taking this medicine.



Pregnancy and breast-feeding

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

Driving and using machines

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

Important information about some of the ingredients of Buscopan Cramps

Buscopan Cramps contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE BUSCOPAN CRAMPS

Always take this medicine exactly as your pharmacist or doctor has told you. You should check with them if you are not sure. BUSCOPAN CRAMPS should not be taken continuously for more than two weeks. Talk to your pharmacist or doctor if you develop new symptoms or if your symptoms get worse or have not improved over two weeks.

Taking this medicine

- Swallow the tablet whole with water
- · Do not crush or chew the tablet

How much to take

For relief of painful spasm of the stomach. bowel or bladder and urinary tubes (urinary

Adults, and children 12 years or over:

 2 tablets four times a day Children 6 to 12 years:

• 1 tablet three times a day Not recommended for children under 6 years

For the relief of abdominal pain in Irritable

Bowel Syndrome (IBS) Adults, and children 12 years or over:

Start by taking 1 tablet three times a dayYou can increase your dose to a maximum of 2 tablets four times a day, if needed Not recommended for children under 12 years

If you take more BUSCOPAN CRAMPS than you should If you take more than you should, talk to a

go to a nospital straight away. Take the medicine pack with you.

If you have any further questions on the use of this product, ask your pharmacist or doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, BUSCOPAN CRAMPS can cause side effects in some people. The following side effects may happen with this medicine:

Mild side effects that do not normally require medical treatment:

Uncommon - affects fewer than 1 in 100 people • Dry mouth

 Abnormal sweating or reduced sweating
If any of these side effects get troublesome or seem serious to you please tell your pharmacist or doctor.

If you get any of the side effects described below stop taking this medicine and tell your doctor straight away. You may need urgent medical treatment:

Uncommon - affects fewer than 1 in 100 people • Skin reactions such as urticaria and pruritus (itching)

• Tachycardia (increased heart rate)

Rare - affects fewer than 1 in 1,000 people Problems emptying the bladder

Isolated events - some side effects are so rare that it is not known how many people may be

- 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. You may have difficulty in breathing and may lose consciousness
- Dyspnoea (difficult or laboured breathing)
- Allergic reactions (hypersensitivity) such as
- skin rash and erythema (patchy red skin) If you experience a painful red eye with loss of vision after taking this medicine, stop taking it and tell your doctor straight away. You may have an eye problem called glaucoma and need urgent medical attention

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 CRAMPS

Do not store above 25°C. Keep in the original packaging.

Keep out of the sight and reach of children.

Do not take BUSCOPAN CRAMPS after the expiry date which you will find printed on the

packaging.

6. FURTHER INFORMATION

What BUSCOPAN CRAMPS contains 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

What BUSCOPAN CRAMPS looks like and

contents of the pack The tablets are white. BUSCOPAN CRAMPS is available in blister packs of 20 tablets.

Marketing Authorisation Holder and Manufacturer

wax, white beeswax and povidone.

The Marketing Authorisation is held by

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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