

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

- contains important information for you to get the best results. Keep this leafiet. 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 leafiet, 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

- 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 Initiable Bowel Syndrome.
 Bowel Syndrome du yupar 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?

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 intolerances • Stimulants 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:

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 intelerant to or cannot digest some sugars (as the tablet coating contains a visue have something called 'myasthenia gravis' (a very rare muscle weakness 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 lieus). Symptoms totols and (or nausea/vormiting • 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 medicine.

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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

- 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 (vring)

You have difficulty or pain passing (urine)
 You have a fever
 You have abnormal vaginal bleeding or
 You have abnormal vaginal bleeding or
 You have abnormal vaginal bleeding or
 You have recently travelled abroad (in case
 you have picked up a stormach bug)
 You have a very fast heart rate or other
 heart problems
 You have been trated by a doctor for a
 severe sweating problem
 If you are not sure if any of the above applies
 to you, taik 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

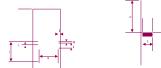
- feeling sick
 being sick
 changes in your bowel movements
 abdominal tenderness
 low blood pressure
 feeling faint or,
 blood in your bowel movements

Taking other medicines Please tell your pharmacist or doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal recent the strategies of the strategies (RAMPS, and the strategies) your of the Redicines cost. Also some other medicines can affect the way BUSCOPAN CRAMPS works.

- In particular tell your pharmacist or doctor if you are taking any of the following medicines:
 Anthistamines used to treat hay fever and other allergies
 Tetracyclic or trucyclic medicines used to theral lergies
 Tetracyclic or trucyclic medicines used to theral severe mental illness such as butyrophenones or phenothiazines used to treat severe mental illness such as schizophrenia
 Dopamine antagonists such as metoclopramide for feeling sick Bata 2 adrenergic medicines such as a duinidine or disopyramide used to control your heart beat
 Anntadine used for Parkinson's disease and flu
 Anticholinergic medicines such as tiotropium, ipratropium or atropine-like medicines usually inhaled to treat
 If you are not sure if any of the above applies to you, takit to your pharmacist or doctor before taking this medicine.

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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 machines.

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

3. HOW TU Take BUSCUPAN CHARN'S Anamatic to an obscupant of the second second second the Anamatic of anticol fue solution, and the chard with them if you are not sure. BUSCOPAN CRAMPS should not be taken continuously for more than two weeks. Talk to your pharmacits 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 bowel or bladder and urmany users of verse tract). 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 Inritable Bowel Syndrome (IBS) Adults, and children 12 years or over: • Start by taking 1 tablet three times a day • You 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 doctor or go to a hospital 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

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

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

Isolated events - some side effects are so rare that it is not known how many people may be affected - 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 consciousnes) - Dysponea (difficult or laboured breathing) - Sheng for and contributed reactions) - Sheng for and contributed reactions - Sheng for and contributed reactions 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 Pearetine - side defact

gialcoma and need urgent medical activition 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

What BUSCOPAN CRAMPS contains Each table contains 10 mg of the active ingredient hyoscine butylbromide. The other ingredients are: calcium hydrogen phosphate, maize starch, soluble starch, colloidal silica, tartaria caid, stearic acid, sucrose, taic, acacia, titanium dioxide, macrogol 6000, carnauba wax, white beswax and povidone.

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 The Marketing Authorisation is held by:

Sanofi 410 Thames Valley Park Drive AID Indines Valley Park Drive Reading Berkshire RG6 IPT 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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