Read all of this leaflet carefully before you start taking BUSCOPAN IBS RELIEF, because it contains important information for you to get the best results.

Avoid this medicine. You may need to use it again.

1. WHAT BUSCOPAN IBS RELIEF IS AND WHAT IT IS USED FOR

BUSCOPAN IBS RELIEF is a tablet containing hyoscine butylbromide. This medicine is to relieve the abdominal cramps which cause pain and discomfort associated with Irritable Bowel Syndrome (IBS). It belongs to a group of medicines called antispasmodics. It works by relaxing the cramping muscles of your bowel.

2. BEFORE YOU TAKE BUSCOPAN IBS RELIEF

Before you take BUSCOPAN IBS RELIEF

• You are allergic to hyoscine butylbromide or any of the other ingredients of BUSCOPAN IBS RELIEF (listed in Section 6).
• You are breast-feeding.
• You are pregnant, likely to get pregnant, or are planning to have a baby.
• You have a very enlarged bowel (megacolon) or bowel obstruction.
• You have a condition where the bowel is not working properly (megacolon or pseudo-obstruction syndrome).
• You have something called 'myasthenia gravis' (a very rare muscle weakness problem).
• You have a very fast heart rate or other heart problems.
• You have been treated by a doctor for a severe mental illness such as schizophrenia.
• You are feeling sick or vomiting.
• You have a fever.
• You have lost your appetite or lost weight.
• You have difficulty or pain passing water.
• You have recently passed blood from the bowel.
• You have severe constipation.
• You have recently travelled abroad (in case you have picked up a stomach bug).
• You have a very fast or irregular heartbeat.
• You have severe abdominal pain with lack of stools and/or nausea/vomiting.
• You have been treated by a doctor for a severe mental illness such as schizophrenia.
• You are taking any of the following medicines:
  • stimulants such as coffee
  • food allergies or intolerances
  • stress, eating and drinking habits
  • sensitive to things like: sugar, fructose, lactose, sorbitol, egg, milk, gluten, yeast, mustard, soya, preservatives, sensitivities, additives or certain other substances.

3. HOW TO TAKE BUSCOPAN IBS RELIEF

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

4. POSSIBLE SIDE EFFECTS

Take special care with BUSCOPAN IBS RELIEF

• Consult with your pharmacist or doctor before taking this medicine if any of the following apply to you, even if you know you have IBS. In case your abdominal pain may be something else:
  • You are 40 years or over and it is some time since your last attack of IBS or the symptoms have been different this time
  • 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 have difficulty or pain passing water.
  • You have a fever.
  • 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 mental illness such as schizophrenia.

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 pains or persistent diarrhoea or constipation.

• Check with your pharmacist or doctor straight away if you have unexplained abdominal pains or persistent diarrhoea or constipation.
• You must contact a doctor if your symptoms worsen or do not improve after two weeks.

In particular, tell your pharmacist or doctor if you are taking any of the following medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because BUSCOPAN IBS RELIEF can affect the way some other medicines work; also some other medicines can affect the way BUSCOPAN IBS RELIEF works.

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5. HOW TO STORE BUSCOPAN IBS RELIEF

• Ask your pharmacist if you need more information or advice.
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6. FURTHER INFORMATION

• Ask your pharmacist if you need more information or advice.
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In particular, tell your pharmacist or doctor if you are taking any of the following medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because BUSCOPAN IBS RELIEF can affect the way some other medicines work; also some other medicines can affect the way BUSCOPAN IBS RELIEF works.
Pregnancy and breast-feeding
Do not take BUSCOPAN IBS RELIEF 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.

3. HOW TO TAKE BUSCOPAN IBS RELIEF
Always take this medicine exactly as your pharmacist or doctor has told you. You should check with them if you are not sure.

BUSCOPAN IBS RELIEF 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.

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
• Swallow the tablet whole with water
• Do not crush or chew the tablet.

BUSCOPAN IBS RELIEF is not recommended for children under 12 years.

If you take more BUSCOPAN IBS RELIEF 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 IBS RELIEF 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
• Dyshidrosis (outbreaks of sweat and dryness of skin)
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 pruritis (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 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.
• 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
This scheme allows you to report more information on the safety of this medicine.

5. HOW TO STORE BUSCOPAN IBS RELIEF
Do not store above 25°C. Keep in the original packaging.

Keep out of the sight and reach of children.

Do not take BUSCOPAN IBS RELIEF after the expiry date which you will find printed on the packaging.

6. FURTHER INFORMATION
What BUSCOPAN IBS RELIEF contains
Each tablet contains 10 mg of the active ingredient hyoscine butylbromide. The other ingredients are: calcium hydrogen phosphate, maize starch, colloidal silica, tartaric acid, sodium, sucrose, talc, acacia, titanium dioxide, macrogol 6000, carnauba wax, white beeswax and propylene.

What BUSCOPAN IBS RELIEF looks like and contents of the pack
BUSCOPAN IBS RELIEF is available in blister packs of 20 and 40 tablets.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation is held by:
Sanofi
One Onslow Street
Guildford
Surrey
GU1 4YS
United Kingdom
Tel: 0845 372 7101
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

This leaflet was revised in October 2017.

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