

**BUSCOPAN**<sup>®</sup>  
IBS Relief

hyoscine butylbromide

sanofi

439247/05/1

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

**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.**

- 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 notice a side effect not listed in this leaflet, please tell your pharmacist or doctor.

**In this leaflet:**

1. What BUSCOPAN IBS RELIEF is and what it is used for
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**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. It belongs to a group of medicines called antispasmodics. It works by relaxing the cramping muscles of your bowel.

**What is Irritable Bowel Syndrome (IBS)?**

Irritable Bowel Syndrome is often just called 'IBS'. Although the precise cause is unknown, the muscles of the 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 bowel. You may also feel bloated, with excess wind and abdominal discomfort. Sometimes IBS can include diarrhoea or constipation.

**2. BEFORE YOU TAKE BUSCOPAN IBS RELIEF**

**Only take BUSCOPAN IBS RELIEF if your doctor has said that you have Irritable Bowel Syndrome.**

**Do not take BUSCOPAN IBS RELIEF if:**

- You are allergic to hyoscine butylbromide or any of the other ingredients of BUSCOPAN IBS RELIEF (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 medicine.

**Take special care with BUSCOPAN IBS RELIEF**

Check with your pharmacist or doctor before taking your 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 are 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 (urine)
- 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 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 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 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.

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

- Antihistamines - used to treat hayfever 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 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.

#### **Important information about some of the ingredients of Buscopan IBS Relief**

Buscopan IBS Relief 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 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
  - 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 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 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](http://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 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, soluble starch, colloidal silica, tartaric acid, stearic acid, sucrose, talc, acacia, titanium dioxide, macrogol 6000, carnauba wax, white beeswax and povidone.

#### **What BUSCOPAN IBS RELIEF looks like and contents of the pack**

The tablets are white. BUSCOPAN IBS RELIEF is available in blister packs of 8, 10, 12, 20, 24, 40, 48, 50, 56 and 60 tablets. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation is held by: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, United Kingdom. Tel: 0800 035 2525 Email: [uk-medicalinformation@sanofi.com](mailto:uk-medicalinformation@sanofi.com)

and the tablets are manufactured by:

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This leaflet was revised in August 2023



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