

Package leaflet: Information for the patient

Sigmopan IBS Relief 10 mg film-coated Tablets

hyoscine butylbromide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read 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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Sigmopan IBS Relief tablets are and what they are used for

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

Sigmopan IBS Relief Tablets are used to relieve the abdominal cramps which cause pain and discomfort associated with Irritable Bowel Syndrome.

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. What you need to know before you take Sigmopan IBS Relief tablets

Only take Sigmopan IBS Relief tablet if your doctor has said that you have Irritable Bowel Syndrome.

Do not take Sigmopan IBS Relief tablet if:

- You are allergic (hypersensitive) to hyoscine butylbromide or any of the other ingredients (listed in section 6)
- You are intolerant to or cannot digest some sugars (as the tablet contains lactose monohydrate)
- 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 Sigmopan IBS Relief Tablets

Check with your doctor or pharmacist 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 are feeling sick or vomiting
- You have lost your appetite or lost weight
- 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 difficulty or pain passing water (urine) such as men with prostate problems
- You have severe constipation
- You have a fever
- You have been treated by a doctor for a severe sweating problem

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Sigmopan IBS Relief 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 Sigmopan IBS Relief Tablets can affect the way some other medicines work. Also some other medicines can affect the way Sigmopan IBS Relief Tablets work.

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

- Tetracyclic or tricyclic medicines - used to treat depression and some types of pain
- Antihistamines - used to treat hayfever and other allergies
- 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
- Anticholinergic medicines such as tiotropium, ipratropium or atropine-like medicines – usually inhaled to treat breathing problems

- Amantadine – used for Parkinson’s disease and flu

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

Pregnancy and breast-feeding

Do not take Sigmopan IBS Relief Tablets 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 Sigmopan IBS Relief Tablets

Sigmopan IBS Relief Tablets contain 70 mg lactose monohydrate. 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 Sigmopan IBS Relief 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. Sigmopan IBS Relief Tablets 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 Sigmopan IBS Relief tablet three times a day
- You can increase your dose to a maximum of 2 Sigmopan IBS Relief tablets four times a day, if needed
- Swallow the Sigmopan IBS Relief tablet whole with water
- Do not crush or chew the Sigmopan IBS Relief tablet

Sigmopan IBS Relief tablet is not recommended for children under 12 years..

If you take more Sigmopan IBS Relief Tablets than you should

If you take more Sigmopan IBS Relief 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 Sigmopan IBS Relief Tablets left.

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

4. Possible side effects

Like all medicines, hyoscine can cause side effects, although not everybody gets them.

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.

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:

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)
- 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 or 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 Sigmopan IBS Relief Tablets

Keep this medicine out of the sight and reach of children.

Do not use after the expiry date stated on the carton (EXP). The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sigmopan IBS Relief tablets contain

- The active substance is Hyoscine butylbromide.
- Each Sigmopan IBS Relief tablet contains 10 milligram of Hyoscine butylbromide.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (Type A), magnesium stearate, talc, tartaric acid.
- Film-coating material of Sigmopan IBS Relief tablet are Opadry II white (Polyvinyl Alcohol, Titanium dioxide, Macrogol/PEG, Talc).

What Sigmopan IBS Relief Tablets look like and contents of the pack

Sigmopan IBS Relief tablets are white coloured round shaped convex film-coated tablets, plain on both sides (Diameter: 6.60 mm).

Sigmopan IBS Relief tablets are packed in blisters containing 10, 20, 24, 40, 56, 60 tablets.

Not all pack size may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder Name and address:

RIA Generics Limited
36 Ingleby Way, Wallington
Surrey, SM6 9LR, United Kingdom

Manufacturer

RIA Generics Limited
36 Ingleby Way, Wallington
SM6 9LR, United Kingdom

If you would like this leaflet in a different format or register a complaint, please contact the Marketing Authorisation holder listed above.

If you would like to have any further information or want to report any side effects, please email at safety@riagenerics.com or phone on +447816860664.

This leaflet was last revised in December 2025.