

Package leaflet: information for the user

Sigmopan 10 mg film-coated tablets (hyoscine butylbromide)

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

Always use this medication 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days

What is in this leaflet

1. What Sigmopan is and what it is used for
2. What you need to know before you take Sigmopan
3. How to take Sigmopan
4. Possible side effects
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1. What Sigmopan is and what it is used for

Sigmopan contains the active substance hyoscine butylbromide.

This medication is used to relieve cramps (spasmolytic). It is used to treat spasms (cramps) in the gastrointestinal tract.

Hyoscine butylbromide 10 mg film-coated tablets is indicated in adults and children over 6 years of age.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2. When you need to know before you use Sigmopan

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. These substances can be found in section 6 of this leaflet.
- You suffer from a certain abnormality of the large intestine (megacolon).
- You suffer from intestinal blockage.
- You have narrowing in the gastrointestinal tract (stenosis).
- You have a certain muscle disease (myasthenia gravis).

When should you be extra careful with this medicine?

- If you have attacks of cramping pains due to gall or kidney stones. In these cases, Sigmopan does not work. Spasms (or resulting pain) may be a symptom of a serious underlying condition.
- If you have glaucoma (an eye problem).
- If you have an increased risk of blockages (obstructions) in the intestines and/or urinary tract.
- If you have heart problems (such as arrhythmias)

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

Contact your doctor or pharmacist immediately if you have unexplained abdominal pain that persists, worsens or occurs simultaneously with symptoms such as fever, nausea, vomiting, changes in bowel habits, tenderness in the lower abdomen, low blood pressure, fainting or blood in the stool.

Children

This medicine is not recommended for children under 6 years of age.

Are you taking any other medications?

Are you taking any other medications besides Sigmopan, or have you recently done so or are you likely to do so soon? Please tell your doctor or pharmacist.

If you use Sigmopan together with one of the following medicines, the effect of one of the two medicines may be influenced:

- certain medications for depression (tri- and tetracyclic antidepressants)
- certain allergy medications (antihistamines)
- certain medications for psychosis (antipsychotics)
- certain medications to regulate your heart rhythm (such as quinidine or disopyramide)
- a medicine for Parkinson's disease and the flu (amantadine)
- certain medications commonly used for breathing problems, such as tiotropium, ipratropium or atropine-like medications
- certain medications that counteract the effect of dopamine (including metoclopramide and domperidone) – this can reduce the effect of both medications
- medications that increase heart rate; the effect of these medications can be enhanced
- substances with the same effect as Sigmopan; this can influence the effects.

Pregnancy and breast-feeding

Are you pregnant, do you think you are pregnant, do you want to become pregnant or are you breastfeeding? Please contact your doctor or pharmacist before using this medication.

There is insufficient data on the use of Sigmopan during pregnancy in humans to assess the potential harm. Use of Sigmopan during pregnancy is therefore not recommended.

There is also insufficient data available regarding use during breastfeeding to assess the possible harmful effects. Therefore, the use of Sigmopan is not recommended during breastfeeding.

Driving and using machines

No studies have been conducted on the effects on the ability to drive and use machines.

Sigmopan contains lactose

This medication contains 70.00 mg lactose (as monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medication.

3. How to take Sigmopan

Always use this medication exactly as stated in this leaflet or as your doctor or pharmacist has told you. Are you unsure about the correct use? Please contact your doctor or pharmacist.

Adults and children from 6 years

The recommended dose is 1 to 2 tablets 3 to 5 times a day.

This medication should not be used day in and day out or for extended periods of time without your doctor investigating the cause of your abdominal pain.

You should swallow the tablets whole with some water or milk (do not chew).

Use in children

Hyoscine butylbromide 10 mg film-coated tablets are not recommended for children under 6 years

If you use more Sigmopan than you should

If you take too much of this medicine, you may experience increased heart rate, dry mouth, blurred vision, retention of urine, redness of the skin and reduced stomach and intestinal function. These side effects are usually mild and short-lived.

Do you experience these symptoms? Then stop taking this medication and contact your doctor.

If you stop using Sigmopan

Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

If you suddenly stop using this medication, the symptoms you had before use may return.

Do you have any other questions about the use of this medication? Please contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can have side effects. Not everyone has to deal with that.

Many of the side effects listed below can be attributed to the action of this drug. These side effects are generally mild and short-lived.

Some side effects can be serious. How often these side effects occur cannot be determined exactly, but they certainly occur in less than 1 in 100 users. **Stop taking this medication and see your doctor immediately** if you notice any of the following serious side effects:

- Severe allergic reactions, together with a sharp drop in blood pressure, paleness, agitation, weak rapid pulse, sweating and reduced consciousness due to a sudden, strong vasodilation (anaphylactic shock)
- Severe, life-threatening allergic reaction to certain substances (anaphylactic reaction).

Other side effects

Some side effects may occur uncommonly (affecting less than 1 in 100 people):

- Skin reactions
- Increased heart rate (tachycardia)
- Dry mouth
- Abnormal sweating or decreased sweating
- Itchy rash (urticaria)
- Itch

Some side effects may occur rarely (affecting less than 1 user in 1,000):

- Not being able to urinate (urinary retention)

The following side effects have also been reported, but it is not known how often they occur:

- Shortness of breath (dyspnea)
- Hypersensitivity
- Skin rash
- Redness of the skin (erythema)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you help provide more information on the safety of this medicine.

5. How to store Sigmopan

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

Do not use this medicine after the expiry date which is stated on the box and blister after EXP. The expiry date refers to the last day of that month.

There are no special storage conditions for this medicine

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sigmopan contains

- The active substance in this medicine is hyoscine butylbromide.

- Each tablet contains 10 milligrams of hyoscine butylbromide.
The other ingredients in this medicine are lactose monohydrate, microcrystalline cellulose (E460), sodium starch glycollate (Type A), magnesium stearate (E470b), talc (E553b), tartaric acid (E344).
Film Coating: Opadry II White (85F28751) - [Polyvinyl alcohol (E1203), Titanium dioxide (E171), Macrogol/PEG (E1521), Talc (E553b)].

What Sigmopan looks like and contents of the pack

Sigmopan are white, round, biconvex, film-coated tablets with a diameter of 6.60 mm, plain on both sides.
The tablets are packed in PVC/PVdC/Alu blisters of 10, 20, 24, 40, 56, 60 & 100 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Name and address:

RIA Generics Limited
The Black Church
St. Mary's Place, Dublin 7
D07 P4AX, Ireland

Manufacturer

RIA Generics Limited
Cube Building, Monahan Road
Cork, T12 H1XY
Ireland

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

Ireland- Sigmopan 10 mg film-coated tablets

Netherlands- Sigmopan 10 mg filmomhulde tabletten

Portugal- Butilescopolamina Novumgen 10 mg comprimidos revestidos por película

Spain- Butilescopolamina Novumgen 10 mg comprimidos recubiertos con película EFG.

This leaflet was last revised in February 2026.