

Buscopan®10mg Coated Tablets

(hyoscine butylbromide)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking Buscopan 10mg Coated Tablets, because it contains important information for you.

- Keep this leaflet. You may need to use it again.
- Ask your pharmacist if you need more information or advice.
- You must stop taking and talk to your pharmacist or doctor if you do not feel better after two weeks of treatment, or if you feel worse.
- If you get any side effects, talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Buscopan 10mg Coated Tablets are and what they are used for
2. What you need to know before you take Buscopan 10mg Coated Tablets
3. How to take Buscopan 10mg Coated Tablets
4. Possible side effects
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1. What Buscopan 10mg Coated Tablets are and what they are used for

Buscopan 10mg Coated Tablets are tablets that contain ‘hyoscine butylbromide’. They belong to a group of medicines called ‘anti-spasmodics’.

This medicine is used to relieve abdominal cramps which cause pain and discomfort associated with your digestive tract, and in Irritable Bowel Syndrome (IBS). It works by relaxing the cramping muscles of your stomach and bowel.

What are abdominal cramps?

Abdominal cramps (or spasms) are due to the sudden, irregular tightening up of muscles in the wall of your stomach or bowel.

What is Irritable Bowel Syndrome (IBS)?

Irritable Bowel Syndrome or IBS is a group of symptoms that can include abdominal pain, cramps, spasms, bloating, and a change in bowel habit (diarrhoea or constipation). These symptoms may come and go over a period of time and you may not have all these symptoms. You can use Buscopan 10mg Coated Tablets to help relieve the pain of the cramping spasm but it is important to see a doctor to then have a diagnosis of IBS confirmed.

While the precise cause of abdominal cramps and IBS 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

These 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.

2. What you need to know before you take Buscopan 10mg Coated Tablets

Do not take Buscopan 10mg Coated Tablets if:

- You are allergic to hyoscine butylbromide or any of the other ingredients of Buscopan 10mg Coated Tablets (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.

Warnings and precautions

Talk to your pharmacist or doctor straight away if you have unexplained abdominal pain which persists or worsens or occurs with:

- fever
- feeling sick or being sick
- changes in your bowel movements
- blood in your stools
- abdominal tenderness
- feeling faint due to low blood pressure

Talk to your pharmacist or doctor before taking Buscopan 10mg Coated Tablets if any of the following applies to you. This is in case your abdominal pain is something else:

- If this is the first time you have had symptoms of Irritable Bowel Syndrome
- You are 40 years or over and it is some time since your last attack of abdominal cramps or IBS or the symptoms are different this time
- You have recently passed blood in your stools
- You have severe constipation
- You are feeling sick or being sick
- 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
- You have abnormal vaginal bleeding or discharge

If any of the above applies to you (or you are not sure), talk to your pharmacist or doctor before taking this medicine even if you have diagnosed IBS. This is in case your abdominal pain is something else.

Children

This medicine is not recommended for children under 12 years of age.

Other medicines and Buscopan 10mg Coated Tablets

Tell your pharmacist or doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Buscopan 10mg Coated Tablets can affect the way some other medicines work; also some other medicines can affect the way Buscopan 10mg Coated Tablets work.

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

- Antihistamines - to treat hayfever and other allergies
- Tetracyclic or tricyclic medicines - to treat depression and some types of pain
- Antipsychotic medicines such as butyrophenones or phenothiazines - 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 – to control your heart beat
- Amantadine – for Parkinson's disease and flu
- Anticholinergic medicines such as tiotropium, ipratropium or atropine-like medicines – usually inhaled to treat breathing problems

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

Pregnancy and breast-feeding

Do not take Buscopan 10mg Coated Tablets if you are pregnant, think you may be pregnant, are planning to have a baby 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.

Buscopan 10mg Coated Tablets contain sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Buscopan 10mg Coated Tablets

Always take this medicine exactly as your pharmacist or doctor has told you. Check with them if you are not sure.

Do not take Buscopan 10mg Coated Tablets continuously for more than 2 weeks.

- Stop taking and talk to your pharmacist or doctor if you do not feel better after 2 weeks

Also stop taking and talk to your pharmacist or doctor if:

- you get new symptoms
- your symptoms get worse

Abdominal cramps

Adults and children 12 years or over:

- 2 tablets four times a day

Irritable Bowel Syndrome

Adults and children 12 years or over:

- Start by taking 1 tablet up to 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 10mg Coated Tablets are not recommended for children under 12 years.

If you take more Buscopan 10mg Coated Tablets 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 medicine, ask your pharmacist or doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Serious side effects

Stop taking this medicine and tell your doctor straight away if you notice any of the following.

You may need urgent medical treatment:

Uncommon: may affect up to 1 in 100 people

- Skin reactions that cause itching (such as urticaria and pruritis)
- Increased heart rate (tachycardia)

Rare: may affect up to 1 in 1,000 people

- Problems emptying the bladder

Not known: these are so rare it is not known how many people may be affected

- Anaphylactic reaction and shock - a severe type of allergic reaction. An itchy rash may spread all over your body, as well as swelling. You may have difficulty in breathing and may lose consciousness
- Difficult or laboured breathing (dyspnoea)
- Allergic reactions (hypersensitivity) such as skin rash and patchy red skin (erythema)
- A painful red eye with loss of vision - you may have an eye problem called 'glaucoma'

Stop taking this medicine and tell your doctor straight away if you notice any of the serious side effects above.

Other side effects

Tell your doctor or pharmacist if the following side effects get troublesome or seem serious to you.

These are usually mild and do not normally require medical treatment:

Uncommon: may affect up to 1 in 100 people

- Dry mouth
- Constipation
- Abnormal sweating or reduced sweating

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 national reporting system (see details below):

HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Buscopan 10mg Coated Tablets

- 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 foil and carton label. The expiry date (EXP) refers to the last day of that month.
- Store below 30°C.
- Store in the original package in order to protect from light.
- 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 Buscopan 10mg Coated Tablets contains

- The active substance is hyoscine butylbromide
- Each tablet contains 10mg of hyoscine butylbromide
- The other ingredients are calcium hydrogen phosphate anhydrous, maize starch, starch soluble, silica colloidal anhydrous, tartaric acid, stearic/palmitic acid, sucrose, talc, acacia, titanium dioxide (E171), macrogol 6000, carnauba wax, beeswax white and povidone.

What Buscopan 10mg Coated Tablets looks like and contents of the pack

- The tablets are round, white, biconvex sugar-coated tablets.
- Buscopan 10mg Coated Tablets are available in blister packs of 20 and 40 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation is held by:
Opella Healthcare France SAS, T/A Sanofi,
82 Avenue Raspail,
94250 Gentilly,
France.
Tel: 353 1 4035600
Email: IEmedinfo@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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