

BUSCOPAN® TABLET

Hyoscine butylbromide (10 mg)

What is in this leaflet

1. What Buscopan® is used for
2. How Buscopan® works
3. Before you use Buscopan®
4. How to use Buscopan®
5. While you are using it
6. Side effects
7. Storage and Disposal of Buscopan®
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Buscopan® is used for

Buscopan® are used to relieve cramps in the muscles of your:

- Stomach
- Gut (intestine)
- Bladder and the tubes that lead to the outside of your body (urinary system)

How Buscopan® works

Buscopan® contain a medicine called “Hyoscine-N-butylbromide”. This belongs to a group of medicines called “antispasmodics”.

Hyoscine works by relaxing the muscle found in the walls of the stomach, and bowel. This type of muscle is called smooth muscle or involuntary muscle. It normally contracts and relaxes without our conscious control and we are not normally aware of it. However, if the muscles go into spasm, this can cause pain.

Hyoscine stops the spasms in the smooth muscle, allowing it to relax. This reduces the painful spasms and cramps.

Before you use Buscopan®

-When you must not use it

Do not take Buscopan® if:

- You are allergic (hypersensitive) to hyoscine butylbromide or any of the other ingredients (listed in Product Description)
- 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).

If you are not sure, talk to your doctor or pharmacist before taking this medicine.

-Before you start to use it

Take special care with Buscopan®

Check with your doctor or pharmacist before taking your medicine if:

- You have a very fast heart rate or other heart problems
 - You have a problem with your thyroid gland such as an overactive thyroid gland
 - You have difficulty or pain passing water (urine) such as men with prostate problems
 - You have constipation
 - You have a fever
 - You are pregnant, likely to get pregnant, or are breast-feeding
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Buscopan®.

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 Buscopan® can affect the way some other medicines work. Also some other medicines can affect the way Buscopan® work.

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

- Medicines for depression called “tetracyclic antidepressants” or “tricyclic antidepressants”
- Medicines for allergies and travel sickness called “antihistamines”

- Medicines to control your heart beat such as quinidine or disopyramide
- Medicines for severe mental illness called ‘antipsychotics’ such as haloperidol or fluphenazine

- Medicines usually used for breathing problems such as tiotropium, ipratropium or atropine-like medicines

- Amantadine - for Parkinson’s disease and flu

- Metoclopramide - for feeling sick (nausea)

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

How to use Buscopan®

-How much to use

Adults and children over 6 years

1 - 2 tablets 3 - 5 times daily.

The tablets should be swallowed whole with adequate fluid.

Buscopan® are not recommended for children under 6 years.

-When to use it

Take Buscopan® at about the same time each day, unless your doctor tells you otherwise.

-How long to use it

Buscopan® should not be taken continuously for long periods of time.

-If you forget to use it

If you forget to take Buscopan®

- If you forget a dose, take it as soon as you remember.

However, if it is time for the next dose, skip the missed dose.

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

-If you use too much (overdose)

If you take more Buscopan® 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 Buscopan® left.

While you are using it

-Things you must do

Buscopan® contain sucrose. Talk to your doctor before taking this medicine if they have told you that you cannot tolerate or digest some sugars.

-Things you must not do

Buscopan® should not be taken on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

-Things to be careful of

Driving and using machines

Some people may have sight problems while taking this medicine. If this happens to you, wait until your sight returns to normal before driving or using any tools or machines.

Side Effect

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

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:

- Allergic reactions such as skin reactions e.g. nettle rash, itching rash, redness of the skin
- Severe allergic reactions (anaphylactic shock) such as difficulty breathing, feeling faint or dizzy
- Painful red eye with loss of vision

Other side effect

- Dry mouth (affects fewer than 1 in 100 people)
- Abnormal sweating or reduced sweating (affects fewer than 1 in 100 people)
- Increased heart rate (affects fewer than 1 in 100 people)
- Being unable to pass water (urine) (affects fewer than 1 in 1,000 people)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers →Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Buscopan®

-Storage

- Do not take this medicine after the expiry date which is printed on the packaging
- Buscopan® should be stored below 30°C
- Keep this medicine out of the sight and reach of children

-Disposal

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.

Product Description

-What it looks like

Buscopan® are sugar-coated, round, biconvex and white in colour.

-Ingredients:

- Active ingredients:Hyosicine butylbromide 10 mg
- Inactive ingredients: calcium hydrogen phosphate (anhydrous), maize starch, colloidal silica (anhydrous), tartaric acid, stearic acid, sucrose, talc, acacia, titanium dioxide, macrogol 6000, carnauba wax, white beeswax, povidone, Ethanol anhydrous and purified water.

-MAL Numbers:

MAL09051577ACZ

Manufacturer

Delpharm Reims
10 Rue Colonel Charbonneaux, 51100 Reims, France.

Product Registration Holder Sanofi-aventis (Malaysia) Sdn. Bhd. Unit TB-18-1, Level 18-1, Tower B, Plaza 33, No.1 Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

Date of revision

24/02/2025

Serial Number

NPRA (R1/1) 20122024/233