

Buscopan® Rx 10 mg tablets

(hyoscine butylbromide)

Package Leaflet: Information for the User

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT BUSCOPAN Rx 10MG COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Buscopan Rx 10mg Coated Tablets contain a medicine called “hyoscine butylbromide”. This belongs to a group of medicines called “antispasmodics”.

Buscopan Rx 10mg Coated Tablets 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)

2. BEFORE YOU TAKE BUSCOPAN Rx 10MG COATED TABLETS

Do not take Buscopan Rx 10mg Coated Tablets if:

- You are allergic (hypersensitive) to hyoscine butylbromide or any of the other ingredients (listed in section 6)
- 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 Buscopan Rx 10mg Coated Tablets

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 a blockage of your gut or problems with your bowels
- You have a fever

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Buscopan Rx 10mg Coated 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 Buscopan Rx 10mg Coated Tablets can affect the way some other medicines work. Also some other medicines can affect the way Buscopan Rx 10mg Coated Tablets 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” such as doxepin
- 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 “anti-psychotics” 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 Rx 10mg Coated Tablets.

Pregnancy and breast-feeding

Do not take Buscopan Rx 10mg Coated Tablets if you are pregnant, likely to get pregnant or are breast-feeding.

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.

Important information about some of the ingredients of Buscopan Rx 10mg Coated Tablets

Buscopan Rx 10mg Coated Tablets contain sucrose. Talk to your doctor before taking this medicine if they have told you that you cannot tolerate or digest some sugars.

3. HOW TO TAKE BUSCOPAN Rx 10MG COATED 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. Buscopan Rx 10mg Coated Tablets should not be taken continuously for long periods of time.

Taking this medicine

- Take your tablets with water
- Do not break, crush or chew the tablets

How much to take

Adults and children over 12 years

- The usual dose is two tablets 4 times a day

Children 6 - 12 years

- The usual dose is one tablet 3 times a day

Buscopan Rx 10mg Coated Tablets are not recommended for children under 6 years.

If you take more Buscopan Rx 10mg Coated Tablets than you should

If you take more Buscopan Rx 10mg Coated 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 Buscopan Rx 10mg Coated Tablets left.

If you forget to take Buscopan Rx 10mg Coated Tablets

- 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Buscopan Rx 10mg Coated Tablets 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 (affects fewer than 1 in 100 people), rash, redness of the skin
- Severe allergic reactions (anaphylactic shock) such as difficulty breathing, feeling faint or dizzy (shock)
- Painful red eye with loss of vision

Other side effects

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

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance
Website: www.hpra.ie

Malta

ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. HOW TO STORE BUSCOPAN Rx 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 Rx 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 Rx 10mg Coated Tablets looks like and contents of the pack

- The tablets are round, white, biconvex sugar-coated tablets
- The tablets are available in blister packs of 56 tablets

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations are held by:

Ireland

Opella Healthcare France SAS
157 avenue Charles de Gaulle
92200 Neuilly-sur-Seine
France.

Malta

Opella Healthcare France SAS
157 avenue Charles de Gaulle
92200 Neuilly-sur-Seine

France.

and the tablets are manufactured by:

Istituto De Angeli S.r.l.
Località Prulli n. 103/c
50066 Reggello (FI)
Italy

For any information about this medicine, please contact the distributor & local representative of the Marketing Authorisation Holder:

Clonmel Healthcare Ltd.,
Waterford Road, Clonmel,
Co. Tipperary, Ireland.
Tel: +353 52 617 7777
Email: medicalinformation@clonmel-health.ie

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