

PACKAGE LEAFLET: INFORMATION FOR THE USER

BUSCOPAN

10 mg film-coated tablet

BUTYLSCOPOLAMINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What BUSCOPAN is and what it is used for
2. Before you take BUSCOPAN
3. How to take use BUSCOPAN
4. Possible side effects
5. How to store BUSCOPAN
6. Further information

1. WHAT BUSCOPAN IS AND WHAT IT IS USED FOR

Buscopan Tablets contain a medicine called “hyoscine butylbromide”. This belongs to a group of medicines called “antispasmodics”. Spasmolytic medicines are those medicines that relax the spasms of internal organs, for example, digestive, urinary and female reproductive organs and thus reduce pain. They are used for the reduction of pain caused by colic (abdominal pain characterized by waves of high and low intensity without precisely specified locations) and pains that are felt in the abovementioned organs.

Buscopan is indicated for the short term treatment of spasm of smooth muscle in the gastrointestinal and genitourinary system (stomach, intestine, gall bladder, urinary tract). It is also used in cases of renal colic, gastrointestinal spasms of various organs, irritable bowel syndrome and painful menstruation.

2. BEFORE YOU TAKE BUSCOPAN

Do not take BUSCOPAN

- If you are allergic (hypersensitive) to hyoscine butylbromide or any of the other ingredients (listed in section 6)
- if you have glaucoma (an eye problem)
- if you have megacolon (a very enlarged bowel)
- if you have something called “myasthenia gravis” (a very rare muscle weakness problem)

- If you have an intolerance to some sugars, because this medicine contains sucrose

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

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

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

Check with your doctor or pharmacist straight away if you have unexplained abdominal pain which persists or worsens or occurs with fever, nausea, vomiting, changes in your bowel movements, abdominal tenderness, low blood pressure, feeling faint or blood in your bowel movements. Your doctor will conduct appropriate diagnostic measures to investigate the cause of the abdominal pain.

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 Tablets can affect the way some other medicines work. Also some other medicines can affect the way Buscopan 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 “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 Tablets.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

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

Driving and using machines

The studies about the effects on the ability to drive and use machines have not been conducted. However, during treatment with Buscopan tablets you may experience side effects such as disturbance of eye adaptation (Difficulty focusing). Therefore, if you notice this side effect, do not use any tools or operate vehicles and machinery.

Important information about some of the ingredients of Buscopan Tablets

One 10 mg tablet contains 41.2 mg of sucrose, which is 411.8 mg sucrose per maximum recommended daily dose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Buscopan 10 mg coated tablets.

3. HOW TO TAKE BUSCOPAN

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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

There is not enough data on the efficacy and safety of Buscopan in children younger than 12 years.

If you need to take Buscopan daily, over a long period of time, contact your doctor to examine the cause of abdominal pain.

If you take more BUSCOPAN than you should

In case of overdose contact your doctor immediately so that you can be provided with immediate medical help. The symptoms that you can expect: dry mouth, redness of the skin, difficulty with urination, rapid heartbeat, constipation and vision disorder.

If you forget to take BUSCOPAN

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

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

If you stop taking BUSCOPAN

Buscopan should be used only when necessary and the treatment should be discontinued after the relief of symptoms.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

Immune system disorders

Uncommon: skin reactions (eg, hives, itching)

Not known: anaphylactic shock, anaphylactic reaction, dyspnea, rash, redness and other reactions of hypersensitivity

Cardiac disorders

Uncommon: rapid heartbeat

Gastrointestinal disorders

Uncommon: dry mouth

Skin and subcutaneous tissue

Uncommon: sweating disorders

Renal and urinary disorder

Rare: difficulty urinating

You may experience vision disorder (disturbance of eye adaptation) and constipation.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE BUSCOPAN

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use BUSCOPAN after the expiry date which is stated on the label, 5 years from the date of manufacture.

6. FURTHER INFORMATION**What BUSCOPAN contains****Active substance:**

1 coated tablet contains: 10 mg of hyoscine butylbromide

Other ingredients:

Core: Calcium hydrogen phosphate, anhydrous; Corn starch, dried; Corn Starch, soluble; Silica, colloidal anhydrous; Tartaric acid; Stearic acid.

Coating: povidone; sucrose; talc; Gum arabic; Titanium dioxide; polyethylene glycol; Carnauba wax; White wax.

What BUSCOPAN looks like and contents of the pack

Round, biconvex, white coated tablets.

Box of 20 coated tablets (2 blisters of 10 tablets).

PVC / PVDC / Alu blister

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Delpharm Reims

10 rue Colonel Charbonneaux

Reims, France