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 you think this leaflet has not been given to you or you have any questions about it, talk to your doctor or pharmacist.

In this leaflet:
1. What BUSCOPAN Tablets are and what they are used for
2. Before you take BUSCOPAN Tablets
3. How to take BUSCOPAN Tablets
4. Possible side effects
5. How to store BUSCOPAN Tablets
6. Further information

1. WHAT BUSCOPAN TABLETS ARE AND WHAT THEY ARE USED FOR

BUSCOPAN Tablets contain a medicine called "hyoscine butylbromide". This belongs to a group of medicines called "antispasmodics".

BUSCOPAN 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)

It can also be used to relieve the symptoms of Irritable Bowel Syndrome (IBS).

2. BEFORE YOU TAKE BUSCOPAN TABLETS

Do not take BUSCOPAN 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 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 gland
• You have difficulty with or poor passing of water (urine) such as men with prostate problems
• You have constipation
• If any of the side effects get troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Check with your doctor or pharmacist straight away if you have unexplained abdominal pain which persists or worsens or occurs with:
• Fever
• Feeling 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 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 atropine, ipratropium or anticholinergic 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.

Take special care with BUSCOPAN Tablets

Check with your doctor or pharmacist before taking your medicine if:
• You have a problem with your thyroid gland such as an overactive gland
• You have difficulty with or poor passing of water (urine) such as men with prostate problems

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
Do not take BUSCOPAN 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 Tablets
BUSCOPAN 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 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 Tablets should not be taken continuously for long periods of time.

How much to take

Adults and children over 12 years
- The usual dose is two tablets 4 times a day
- Your doctor may give you a lower starting dose of one tablet 3 times a day. This dose may be increased if further relief is necessary

Children 6 - 12 years:
- The usual dose is one tablet 3 times a day

BUSCOPAN Tablets are not recommended for children under 6 years.

If you take more BUSCOPAN Tablets than you should
If you take more BUSCOPAN Tablets than you should, ask a doctor or go to a hospital straight away. Take the medicine pack with you if there are no BUSCOPAN Tablets left.

If you forget to take BUSCOPAN 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
Some of these side effects may happen with this medicine.

Other side effects
• Dry mouth
• Small blisters on hands and feet
• Increased heart rate
• Being unable to pass urine
• Allergic reactions such as rash, itching, distressing sensations
• Dry skin
• Red eye or loss of vision

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.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

5. HOW TO STORE BUSCOPAN TABLETS
• Do not take this medicine after the expiry date which is printed on the packaging
• BUSCOPAN Tablets should be protected from light and stored in a dry place below 25°C
• Keep this medicine out of the sight and reach of children

6. FURTHER INFORMATION

What BUSCOPAN Tablets contain
Each tablet contains 10 mg of the active ingredient hyoscine butylbromide.

The other ingredients are: calcium hydrogen phosphate, maize starch, soluble starch, colloidal silica, tartaric acid, stevia, sucrose, talc, acacia, titanium dioxide, microcrystalline cellulose, carnauba wax, white beeswax and povidone.

What BUSCOPAN Tablets look like and contents of the pack
BUSCOPAN Tablets are sugar-coated, round and white in colour.

BUSCOPAN Tablets are available in blister packs of 56 and 100 tablets.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation is held by:
Sanofi, One Durnlow Street
Guildford, Surrey
GU1 4PS, United Kingdom
Tel: 0845 372 7101

and the tablets are manufactured by:
Istituto De Angeli S.r.l.
Loc. Prulli, 103/C, 50066 Reggello (FI), Italy.

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