

PATIENT INFORMATION LEAFLET (PIL)

BUSCOMAX (HYOSCINE BUTYLBROMIDE TABLETS BP 10 mg)

Read this entire leaflet carefully before you starts using 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:

- What BUSCOMAX is and what it is used for
- What you need to know before you take BUSCOMAX
- How to take BUSCOMAX
- Possible side effects
- How to store BUSCOMAX
- Contents of the pack and other information

1. WHAT BUSCOMAX IS AND WHAT IT IS USED FOR:

Buscomax 10 mg Tablets are indicated for the relief of spasm of the genito-urinary tract or gastro- intestinal tract and for the symptomatic relief of Irritable Bowel Syndrome.

WHAT YOU NEED TO KNOW BEFORE TAKING BUSCOMAX:

Do not take BUSCOMAX and tell your doctor if:

- You are allergic (hypersensitive) to hyoscine butylbromide or any of the other ingredients
- 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

PATIENT INFORMATION LEAFLET (PIL)

BUSCOMAX (HYOSCINE BUTYLBROMIDE TABLETS BP 10 mg)

medicine.

Take special care with BUSCOMAX 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 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 BUSCOMAX 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

Concomitant use of BUSCOMAX with 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 BUSCOMAX Tablets can affect the way some other medicines work. Also some other medicines can affect the way BUSCOMAX 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

PATIENT INFORMATION LEAFLET (PIL)

BUSCOMAX (HYOSCINE BUTYLBROMIDE TABLETS BP 10 mg)

- 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 BUSCOMAX Tablets.

Pregnancy, breast-feeding

Do not take BUSCOMAX 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.

2. HOW TO TAKE BUSCOMAX :

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. BUSCOMAX 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
- For Irritable Bowel Syndrome, 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
- BUSCOMAX Tablets are not recommended for children under 6 years.

PATIENT INFORMATION LEAFLET (PIL)

BUSCOMAX (HYOSCINE BUTYLBROMIDE TABLETS BP 10 mg)

If you have taken more BUSCOMAX than prescribed

If you take more BUSCOMAX 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 BUSCOMAX Tablets left.

If forget to take BUSCOMAX

- 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.

3. POSSIBLE SIDE EFFECTS :

Like all medicines, BUSCOMAX 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)
- 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).

4. HOW TO STORE BUSCOMAX:

Store below 30°C, protected from light and moisture. Keep the medicine out of reach of children.

PATIENT INFORMATION LEAFLET (PIL)

BUSCOMAX (HYOSCINE BUTYLBROMIDE TABLETS BP 10 mg)

5. PACK CONTENT AND OTHER INFORMATION

What is the composition of BUSCOMAX

Each film coated tablet contains:

Hyoscine Butylbromide BP..... 10 mg

Excipientsq.s

Colour: Titanium Dioxide BP

Excipients:

Maize Starch

Microcrystalline Cellulose

Lactose

Colloidal Silicon Dioxide

PVPK-30

Methyl Paraben Sodium

Propyl Paraben Sodium

Purified Water

Talcum

Magnesium Stearate

Croscarmellose Sodium

Titanium Dioxide

HPMC-15cps

PEG-6000

Isopropyl Alcohol

Methylene Di chloride

Aspect of BUSCOMAX and pack content

10 Tablets are packed in alu/alu blister. Such 10 blister packed in a printed carton with packaging insert.

PATIENT INFORMATION LEAFLET (PIL)

BUSCOMAX (HYOSCINE BUTYLBROMIDE TABLETS BP 10 mg)

6. Supplier and Manufacturer

Manufactured By:

Maxtar Bio-Genics (Formulations division).

K. No. 705, Vill. Malku Majra, Nalagarh Road
(Baddi), Tehsil Nalagarh, Distt. Solan (H.P.)

Pin code- 173205, India.