



Package leaflet: Information for the user

Hyoscine butylbromide 10 mg coated tablets

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. See section 4.

What is in this leaflet:

1. What Hyoscine butylbromide coated tablets are and what they are used for
2. What you need to know before you take Hyoscine butylbromide coated tablets
3. How to take Hyoscine butylbromide coated tablets
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5. How to store Hyoscine butylbromide coated tablets
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1. What Hyoscine butylbromide coated tablets are and what they are used for

Hyoscine butylbromide coated tablets contain a medicine called “hyoscine butylbromide”. This belongs to a group of medicines called “antispasmodics”.

Hyoscine butylbromide coated tablets are used to relieve cramps in the muscles of your:

- Stomach
- Gut (intestine)
- Bladder and 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. What you need to know before you take Hyoscine butylbromide coated tablets

Do not take Hyoscine butylbromide 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 Hyoscine butylbromide 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 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 Hyoscine butylbromide 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, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal medicines. This is because hyoscine butylbromide can affect the way some other medicines work. Also some other medicines can affect the way hyoscine butylbromide works.

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 and 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 Hyoscine butylbromide coated tablets.

Pregnancy and breast-feeding

Do not take Hyoscine butylbromide 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.

Hyoscine butylbromide coated tablets contain Sucrose

Hyoscine butylbromide coated tablets contain sucrose. Talk to your doctor or pharmacist before taking this medicine if they have told you that you cannot tolerate or digest some sugars.

3. How to take Hyoscine butylbromide coated tablets

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Hyoscine butylbromide 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.

Hyoscine butylbromide is not recommended for children under 6 years.

If you take more Hyoscine butylbromide coated tablets than you should

If you take more Hyoscine butylbromide coated tablets than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you even if there are no Hyoscine butylbromide coated tablets left.

If you forget to take Hyoscine butylbromide 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, hyoscine butylbromide 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)

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 via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hyoscine butylbromide coated tablets

- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Hyoscine butylbromide coated tablets should be stored below 30°C.
- 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.
- Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information

What Hyoscine butylbromide coated tablets contains

The active substance is hyoscine butylbromide. Each tablet contains 10 mg hyoscine butylbromide.

The other ingredients are calcium hydrogen phosphate dihydrate, maize starch, tartaric acid, silica colloidal anhydrous, and stearic acid. The tablet coating contains sucrose, talc, hypromellose 2910, glycerol monostearate, triglycerides medium chain, poly vinyl alcohol, macrogol 4000 and polysorbate 80.

What Hyoscine butylbromide coated tablets look like and contents of the pack

Hyoscine butylbromide coated tablets are white to off-white, sugar coated circular, biconvex tablets plain on both sides.

Hyoscine butylbromide coated tablets are marketed in white opaque PVC/PVdC-Aluminium foil blister packs.

Pack sizes: 56 tablets

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