



Appendix 1 - Hyoscine Butylbromide 20 mg Film-coated Tablets, PL 20117/0349 – Patient Information Leaflet (PIL) Copy – Page 1

MORNINGSIDE
HEALTHCARE

PACKAGE LEAFLET: INFORMATION FOR THE USER

Hyoscine Butylbromide

10 mg and 20 mg Film-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 Tablets are and what they are used for
2. What you need to know before you take Hyoscine Butylbromide Tablets
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1. What Hyoscine Butylbromide Tablets are and what they are used for

The name of your medicine is Hyoscine Butylbromide 10 mg and 20 mg Film-coated Tablets (called Hyoscine Butylbromide Tablets in the rest of this leaflet). Hyoscine Butylbromide Tablets contain a medicine called "hyoscine butylbromide". This belongs to a group of medicines called "antispasmodics".

Hyoscine Butylbromide 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. What you need to know before you take Hyoscine Butylbromide Tablets

Do not take Hyoscine Butylbromide Tablets if:

- you are allergic to hyoscine butylbromide or any of the other ingredients of this medicine (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 Hyoscine Butylbromide Tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Hyoscine Butylbromide Tablets 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 applies to you, talk to your doctor or pharmacist before taking Hyoscine Butylbromide 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.

Other medicines and Hyoscine Butylbromide Tablets
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 Tablets can affect the way some other medicines work, and some other medicines can affect the way Hyoscine Butylbromide Tablets work.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- 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 Hyoscine Butylbromide Tablets.

Pregnancy, breast-feeding and fertility
Do not take this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

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 Tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Hyoscine Butylbromide Tablets

Always take your medicine exactly as your doctor or pharmacist has told you. You should



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check with your doctor or pharmacist if you are not sure. Hyoscine Butylbromide 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 recommended dose is two tablets of 10 mg or one tablet of 20 mg 4 times a day.
- For Irritable Bowel Syndrome, your doctor may give you a lower starting dose of one tablet of 10 mg 3 times a day. This dose may be increased, if further relief is necessary.

Children 6 - 12 years:

- The recommended dose is one tablet of 10 mg 3 times a day.

Hyoscine Butylbromide Tablets are not recommended for children under 6 years.

If you take more Hyoscine Butylbromide Tablets than you should

If you take more Hyoscine Butylbromide 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 Hyoscine Butylbromide Tablets left.

If you forget to take Hyoscine Butylbromide Tablets

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Hyoscine Butylbromide Tablets

Do not stop taking Hyoscine Butylbromide Tablets without talking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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 (Uncommon - may affect up to 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 (Uncommon - may affect up to 1 in 100 people).
- Abnormal sweating or reduced sweating (Uncommon - may affect up to 1 in 100 people).
- Increased heart rate (Uncommon - may affect up to 1 in 100 people).
- Being unable to pass water (urine) (Rare - may affect up to 1 in 1,000 people).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 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 blister and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Hyoscine Butylbromide Tablets contain

- The active substance is hyoscine butylbromide. Each film-coated tablet contains either 10 mg or 20 mg of hyoscine butylbromide.
- The other ingredients are:
Tablet core: lactose monohydrate; cellulose, microcrystalline; povidone and magnesium stearate.
Tablet coating: polyvinyl alcohol (E1203), titanium dioxide (E171), talc (E553b), polyethylene glycol (E1521) and lecithin (E422).

What Hyoscine Butylbromide Tablets look like and contents of the pack

Hyoscine Butylbromide 10 mg Film-coated Tablets are white to off-white round, biconvex, film-coated tablets with '10' debossed on one side and plain on other side.

Hyoscine Butylbromide 20 mg Film-coated Tablets are white to off-white round, biconvex, film-coated tablets with '20' debossed on one side and plain on other side.

For both 10 mg and 20 mg tablets pack sizes of 28, 56, 100 and 500 tablets are available.

Not all pack sizes may be marketed.

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This leaflet was last revised in October 2021.

M0346LAMUKNA-P1-001