

T: 0131-244-2528
E: irene.fazakerley@gov.scot

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

21 November 2022

Dear Healthcare Professional,

**DRUG ALERT CLASS 4 DRUG ALERT 48 2022 – CLASS 4 MEDICINES RECALL –
CAUTION IN USE – MORNINGSIDE HEALTHCARE LIMITED – HYOSCINE
BUTYLBROMIDE 20MG FILM-COATED TABLETS**

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 21 November 2022

EL (22)A/48

Our Ref: MDR 057-11/22

Dear Healthcare Professional,

Morningside Healthcare Limited

Hyoscine Butylbromide 20 mg Film-coated Tablets

PL 20117/0349

Batch No	Expiry Date	Pack Size	First Distributed
22237001	04/2025	100	28/09/2022

Active Pharmaceutical Ingredient: hyoscine butylbromide

Brief description of the problem:

Morningside Healthcare Limited has informed the MHRA of an error with the Patient Information Leaflet (PIL) packaged in batch 22237001 of Hyoscine Butylbromide 20 mg Film-coated Tablets. Some packs within the batch may contain a PIL for Midodrine Hydrochloride 2.5 mg & 5 mg Tablets. The issue was identified due to a market complaint, which noted that a Midodrine Hydrochloride 2.5 mg & 5 mg Tablets leaflet had been found in a pack of Hyoscine Butylbromide 20 mg Film-coated Tablets, batch 22237001, expiry date 04/2025.

Advice for healthcare professionals:

Healthcare professionals should note that there is no risk to product quality and efficacy, therefore the affected batch is not being recalled.

Healthcare professionals are advised to exercise caution when dispensing the above batch and to check the PIL. If the pack contains the wrong PIL, it should be removed and destroyed and a copy of the correct PIL provided to the patient. This can be downloaded via the following link: www.medicines.org.uk/emc/files/pil.13314.pdf. Additionally, any patients who may present with the incorrect leaflet should be provided with a correct leaflet.

Morningside Healthcare Limited has also confirmed that all remaining packs of the above batch will not be distributed and that all future batches will contain the updated PIL. Upon request, the manufacturer will post hard copies of the updated PIL to wholesalers and pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information.



Medicines & Healthcare products Regulatory Agency

Advice for patients:

Patients should be aware that some packs of Hyoscine Butylbromide 20 mg Film-coated Tablets may contain a PIL for Midodrine Hydrochloride 2.5 mg & 5 mg Tablets.

- If your pack contains the incorrect PIL, please speak to your local pharmacist to obtain the correct PIL, but you can also download a copy of the correct PIL via the following link: www.medicines.org.uk/emc/files/pil.13314.pdf.
- Please see Appendix 1 of this notification for a full copy of the PIL for information.
- If you have any questions about your medicine or are concerned about side effects, talk to your healthcare professional.
- The medicine itself is not affected and any suspected adverse reactions should be reported via the MHRA [Yellow Card scheme](#).

Hyoscine Butylbromide tablets are used to relieve cramps in the muscles of your: stomach, gut (intestine) and/or, 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). Morningside Healthcare Limited has confirmed that the tablets in the pack of Hyoscine Butylbromide 20 mg Film-coated Tablets remain correct and contain hyoscine butylbromide. This issue only impacts the printed PIL included in the pack.

For information, Midodrine tablets contain the active ingredient midodrine hydrochloride which belongs to a group of medicines called adrenergic and dopaminergic agents. It works by raising your blood pressure and is used to treat certain severe forms of low blood pressure in adults when other treatments have not worked.

Further Information:

For further information please contact: Morningside Healthcare Ltd, Morningside House, Unit C Harcourt Way, Meridian Business Park, Leicester, LE19 1WP, Telephone: +44 (0)116 2045950

For medical information enquiries, please contact: medicalenquiry@morningsidehealthcare.com or Telephone +44 (0)116 478 0322 and for all stock enquiries, please contact Telephone: +44 (0)1162045950

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk



Medicines & Healthcare products Regulatory Agency

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

PACKAGE LEAFLET: INFORMATION FOR THE USER

MORNINGSIDE
HEALTHCARE

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
3. How to take Hyoscine Butylbromide Tablets
4. Possible side effects
5. How to store Hyoscine Butylbromide Tablets
6. Contents of the pack and other information

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



Medicines & Healthcare products Regulatory Agency

Appendix 1 - Hyoscine Butylbromide 20 mg Film-coated Tablets, PL 20117/0349 – Patient Information Leaflet (PIL) Copy – Page 2

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.

Marketing Authorisation Holder

Morningside Healthcare Ltd.
Unit C, Harcourt Way
Leicester, LE19 1WP, UK

Manufacturer

Morningside Pharmaceuticals Ltd.
5 Pavilion Way
Loughborough, LE11 5GW, UK

This leaflet was last revised in October 2021.

M0346LAMUKNA-P1-001