

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

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.

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.

TO ALL CHEMISTS, DOCTORS ON THE LISTS
Telephone No. 028 9536 0333