

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 Hours

Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

B Braun Medical Ltd

Gentamicin 3mg/ml solution for infusion

PL 03551/0117

SNOMED Code:

39394111000001103

Batch Number	Expiry Date	Pack Size	First Distributed
21025402	31/12/2023	120ml Ecoflac Plus	01/03/2021
21056410	31/01/2024	120ml Ecoflac Plus	16/03/2021

Active Pharmaceutical Ingredient: Gentamicin Sulphate

Gentamicin 3mg/ml solution for infusion

PL 03551/0117

SNOMED Code: 39393811000001107

Batch Number	Expiry Date	Pack Size	First Distributed
21056409	31/01/2024	80ml Ecoflac Plus	04/10/2021
21427416	30/09/2024	80ml Ecoflac Plus	10/06/2022

Active Pharmaceutical Ingredient: Gentamicin Sulphate

Glucose Intravenous Infusion BP 5% w/v

PL 03551/0059

SNOMED Code: 39369911000001101

Batch Number	Expiry Date	Pack Size	First Distributed
22041405	31/12/2024	50ml Ecoflac Plus	04/05/2022

Active Pharmaceutical Ingredient: Glucose Monohydrate

Ibuprofen 400mg Solution for Infusion

PL 03551/0152

SNOMED Code: 41049911000001104

Batch Number	Expiry Date	Pack Size	First Distributed
21095409	29/02/2024	100ml Ecoflac Plus	06/07/2021

Active Pharmaceutical Ingredient: Ibuprofen

Ibuprofen 600mg Solution for Infusion

PL 03551/0153

SNOMED Code: 41050211000001103

Batch Number	Expiry Date	Pack Size	First Distributed
21096410	29/02/2024	100ml Ecoflac Plus	06/07/2021

Active Pharmaceutical Ingredient: Ibuprofen

Ibuprofen 200mg Solution for Infusion

PL 03551/0155

SNOMED Code: 41049611000001105

Batch Number	Expiry Date	Pack Size	First Distributed
22133402	28/02/2025	50ml Ecoflac Plus	07/07/2022

Active Pharmaceutical Ingredient: Ibuprofen

Paracetamol 10mg/ml Solution for Infusion

PL 03551/0128

SNOMED Code: 36088811000001109

Batch Number	Expiry Date	Pack Size	First Distributed
21357402	31/08/2023	50ml Ecoflac Plus	24/11/2021
21357403	31/08/2023	50ml Ecoflac Plus	02/11/2021
21423402	30/09/2023	50ml Ecoflac Plus	25/11/2021
21424401	30/09/2023	50ml Ecoflac Plus	02/12/2021

Active Pharmaceutical Ingredient: Paracetamol

Sodium Chloride 0.9% w/v Intravenous Infusion BP

PL 03551/0088

SNOMED Code: 39456411000001100

Batch Number	Expiry Date	Pack Size	First Distributed
21261404	31/05/2024	50ml Ecoflac Plus	16/09/2021
21384403	31/08/2024	50ml Ecoflac Plus	29/10/2021
21433401	30/09/2024	50ml Ecoflac Plus	21/12/2021



22123413	28/02/2025	50ml Ecoflac Plus	11/05/2022
22165411	31/03/2025	50ml Ecoflac Plus	27/05/2022
23104401	28/02/2026	50ml Ecoflac Plus	24/05/2023

Active Pharmaceutical Ingredient: Sodium Chloride

Water for Injections BP, solvent for parenteral use

PL 03551/0077

SNOMED Code: 39504111000001103

Batch Number	Expiry Date	Pack Size	First Distributed
21231404	31/05/2024	100ml Ecoflac Plus	05/10/2021
21387412	31/08/2024	100ml Ecoflac Plus	23/12/2021

Active Pharmaceutical Ingredient: Water for Injection

Fluconazole 2mg/ml solution for infusion

PL 03551/0115

SNOMED Code: 36076811000001100

Batch Number	Expiry Date	Pack Size	First Distributed
21473402	31/10/2023	100ml Ecoflac Plus	21/01/2022
22125401	29/02/2024	100ml Ecoflac Plus	16/06/2022

Active Pharmaceutical Ingredient: Fluconazole

Brief description of the problem

B. Braun Medical Limited is recalling the specific product batches as a precautionary measure after traces of midazolam were detected in the batches listed in this notification. The listed product batches were manufactured following the manufacture of midazolam solution for infusion at the manufacturing facility and therefore some batches were detected to be contaminated with traces of midazolam above the Permitted Daily Exposure (PDE). Based on the analysis, all batches with a confirmed contamination above the safety threshold are included in this notification. Additionally, for solutions that could not be analysed, due to the lack of a reliable method, the batches are also being recalled as a precautionary measure, based on the theoretical risk of midazolam exceeding the safety threshold.

A toxicological assessment has been completed to evaluate the potential risk for patients. The assessment concluded that the highest detected levels of midazolam are deemed to display no clinical effects. Nevertheless, although at low risk, allergic reactions to Midazolam cannot be excluded. B. Braun Medical Limited has not received any reports of suspected adverse drug reactions for the affected batches.

Advice for healthcare professionals

Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Based on the distribution dates, most of the affected stock will have been used already. B. Braun has confirmed that other stock which is not impacted remains available.



Advice for patients

No action is required by patients as this is a Pharmacy and Wholesaler level recall. This product is administered by healthcare professionals directly. If you have concerns about a medicine you may be using, please contact your healthcare professional.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).



Further Information

For stock control enquiries please contact via email or telephone: Josh Watts: Product Manager, email: josh.watts@bbraun.com or telephone: 07973 976257

For information about the recall please contact via email or telephone: Catherine Clulow: Local Vigilance and Project Coordinator, email: recalls.uk@bbraun.com or telephone: 0114 2259155

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

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BT2 8DQ

Telephone No. 028 9536 0333

31st July 2023

Pharmaceutical website: <http://www.hscbusiness.hscni.net>