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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

28 May 2020

Dear Healthcare Professional,

CLASS 4 DRUG ALERT – NO 24 2020 - MEDICINES DEFECT INFORMATION: TORBAY PHARMACEUTICALS (FOR VERITON PHARMA LTD), SODIUM BENZOATE (AMZOATE) 2MG IN 10ML STERILE SOLUTION FOR INJECTION

Please see the attached 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





DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 28 May 2020

EL (20)A/24

Our Ref: MDR 101-05/20

Dear Healthcare Professional,

Torbay Pharmaceuticals (for Veriton Pharma Ltd)

**Sodium Benzoate (Amzoate) 2g in 10 mL Sterile
Solution for injection**

**Unlicensed Medicine -
Y0260J - (MS)**

| Batch Number | Expiry Date | Pack Size | First Distributed |
|---------------------|--------------------|------------------|--------------------------|
| 1902285 | 02/2022 | 10 | 04/04/2019 |
| 1905165 | 05/2022 | 10 | 08/07/2019 |
| 1907165 | 07/2022 | 10 | 18/09/2019 |

**Sodium Benzoate (Amzoate) 2g in 10 mL Sterile
Solution for injection**

**Unlicensed Medicine -
Y9546K - (MIA)**

| Batch Number | Expiry Date | Pack Size | First Distributed |
|---------------------|--------------------|------------------|--------------------------|
| 1807065 | 07/2021 | 10 | 20/08/2018 |
| 1808065 | 08/2021 | 10 | 28/09/2018 |
| 1808075 | 08/2021 | 10 | 28/09/2018 |
| 1808245 | 08/2021 | 10 | 28/09/2018 |
| 1812145 | 12/2021 | 10 | 17/01/2019 |

Brief description of the problem

Torbay Pharmaceuticals has informed us that the carton label on Sodium Benzoate (Amzoate) 2g in 10 mL Sterile Solution for injection incorrectly states the concentration of disodium edetate (excipient) as 0.1% w/v (10mg in 1mL) instead of 0.1% w/v (10mg in 10mL). It should be noted that this product is manufactured as an unlicensed special.

Advice for healthcare professionals

Healthcare professionals are advised to exercise caution when dispensing and administering the product. There is no risk to product quality as a result of this issue, therefore the associated batches are not being recalled at this time.



Further Information

For stock control queries please contact Torbay Pharmaceuticals, Telephone +44 (0)1803 664707 or email torbaypharmaceuticals@nhs.net

For any medical information enquires please contact Torbay Pharmaceuticals, Telephone +44 (0)1803 664707 or email torbaypharmaceuticals@nhs.net

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

Yours faithfully

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