



## **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)**

| <b>Batch Number</b> | <b>Expiry Date</b> | <b>Pack Size</b> | <b>First Distributed</b> |
|---------------------|--------------------|------------------|--------------------------|
| 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)**

| <b>Batch Number</b> | <b>Expiry Date</b> | <b>Pack Size</b> | <b>First Distributed</b> |
|---------------------|--------------------|------------------|--------------------------|
| 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](mailto:torbaypharmaceuticals@nhs.net)

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