



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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