Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Pharmacy and Wholesaler Level

Date: 08 July 2019 EL (19)A/16 Our Ref: MDR 48-02/19

Dear Healthcare Professional,

Martindale Pharma

Phenobarbital Sodium 30mg/ml Injection PL 01883/6188R

Batch Number	Expiry Date	Pack Size	First Distributed
0101620	10/2020	1 x 10	21/12/2018
0102721	11/2020	1 x 10	31/01/2019
0104613	11/2020	1 x 10	05/03/2019
0104155	10/2020	1 x 10	07/01/2019

Brief description of the problem

Martindale Pharma has informed MHRA that the EAN bar code on the above batches is incorrect. The barcode reference should have been 5014124170278 however code 501412470261 was applied to the carton in error. The incorrect barcode scans the batch as Phenobarbital Sodium Injection 200mg/ml.

All other information on the carton and ampoule label is correct for the above batches of Phenobarbital Sodium 30mg/ml Solution for Injection.

The barcode error increases the risk of product mix up when an automated inventory system is used to dispense the affected batch within the pharmacy or wholesale facility.

Advice for pharmacists

The barcode should not be used for any dispensing activities for this batch.
Please bring this notice to the attention of all relevant staff within your facility.

If you have supplied units from this batch to any other pharmacy or clinic, please forward a copy of this Alert to them.

Advice for wholesalers

The barcode should not be used for wholesaling activities for this batch.
Please bring this notice to the attention of all relevant staff within your facility.

If you have supplied units from this batch to any other wholesalers, please forward a copy of this Alert to them.

Further Information

For any enquiries please contact Nick Flynn, Tel: 01708 336 412

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully

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