Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 29 November 2021 EL (21)A/33 Our Ref: MDR 282-11/21

Dear Healthcare Professional,

PilsCo Ltd.

Mometasone Furoate 50 Microgram / Dose Nasal Spray, Suspension

PL 39467/0512

Batch No	Expiry Date	Pack Size	First Distributed
KT1782	31/05/2022	Bottle 18g, corresponding to 140 delivered doses	03/02/2021
KT1781	31/05/2022	Bottle 18g, corresponding to 140 delivered doses	31/03/2021
KV4290	31/07/2022	Bottle 18g, corresponding to 140 delivered doses	12/05/2021
KV4303	31/07/2022	Bottle 18g, corresponding to 140 delivered doses	13/05/2021
KR4651	31/05/2022	Bottle 18g, corresponding to 140 delivered doses	13/05/2021
KV4301	31/07/2022	Bottle 18g, corresponding to 140 delivered doses	25/05/2021
KV4299	31/07/2022	Bottle 18g, corresponding to 140 delivered doses	04/06/2021
KV4302	31/07/2022	Bottle 18g, corresponding to 140 delivered doses	05/07/2021
KY6352	30/09/2022	Bottle 18g, corresponding to 140 delivered doses	13/07/2021
KY6322	30/09/2022	Bottle 18g, corresponding to 140 delivered doses	31/08/2021

Active Pharmaceutical Ingredient: Mometasone Furoate

Brief description of the problem
PilsCo Ltd. have identified a error relating to the wording on the outer carton label. The label affixed on the bottle states: 'use within 2 weeks of first use', instead of the correct label statement which should be: 'use within 2 months of first use'.

The correct statement 'use within 2 months of first use' is printed on the patient information leaflet and on the carton.

Advice for healthcare professionals
There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing the product and instruct the patient to ensure they use the product within 2 months of first use.

Further Information
For more information, medical information queries or stock control queries, please contact:

Nigel Kelly
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Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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