

For Action: Assistant Director Integrated Care, Head of Pharmacy and

Medicines Management, HSC Board & BSO Heads of Pharmacy and Medicines Management of

HSC Trusts

Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer

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Our Ref: PHC/35/2021 Date: 29 November 2021

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Distribute to Pharmacy/Wholesaler Level

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 Nigel@ethigen.co.uk 013555 98155

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely

Mrs Cathy Harrison

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Chief Pharmaceutical Officer