

## MEDICINES NOTIFICATION

#### **CLASS 4 MEDICINES DEFECT INFORMATION**

# Caution in Use Distribute to Pharmacy/Wholesaler Level

Date: 26 April 2023 EL (23)A/15 Our Ref: MDR 133-04/23

Dear Healthcare Professional,

### Omega Pharma Ltd.

**Beconase Hayfever Nasal Spray** 

PL 02855/0064

SNOMED CODE: 2945411000001101

Batch No	Expiry Date	Pack Size	First Distributed
2014041A	04-2023	1	15/4/2021
2014065A	04-2023	1	15/4/2021
2014066A	04-2023	1	16/5/2021
2044014A	10-2023	1	2/6/2021
2044067A	11-2023	1	17/6/2021
2044067B	11-2023	1	21/6/2021
2044068A	11-2023	1	25/6/2021
2044069A	11-2023	1	19/7/2021
2116123A	04-2024	1	14/10/2021
2116124A	04-2024	1	16/12/2021
2116125A	04-2024	1	26/1/2022
2116126A	05-2024	1	22/2/2022
2145069A	12-2024	1	17/3/2022
2145070A	12-2024	1	29/3/2022
2148073A	12-2024	1	5/4/2022
2148074A	12-2024	1	10/4/2022
2150075A	01-2025	1	26/4/2022
2140122A	10-2024	1	3/5/2022
2150076A	01-2025	1	5/5/2022
2140119A	10-2024	1	12/5/2022
2140120A	10-2024	1	5/13/2022
2140121A	10-2024	1	9/6/2022

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## Medicines & Healthcare products Regulatory Agency

2213041A	04-2025	1	4/7/2022
2213042A	04-2025	1	19/7/2022
2213043A	04-2025	1	17/8/2022
2213044A	04-2025	1	7/11/2022
2213045A	04-2025	1	23/12/2022
2239053A	11-2025	1	26/1/2023
2239054A	11-2025	1	8/2/2023
2242070A	12-2025	1	15/2/2023
2242071A	12-2025	1	7/3/2023
2247008A	12-2025	1	7/3/2023
2248058A	12-2025	1	7/3/2023
2247075A	12-2025	1	20/3/2023
2247076A	12-2025	1	21/3/2023
2248057A	12-2025	1	21/3/2023
2247076B	12-2025	1	22/3/2023
2301078A	01-2026	1	30/3/2023
2301084A	01-2026	1	30/3/2023
2301083A	01-2026	1	30/3/2023
2301080A	01-2026	1	3/4/2023
2313009A	03-2026	1	Not yet distributed
2313010A	03-2026	1	Not yet distributed
2313011A	03-2026	1	Not yet distributed
2313012A	04-2026	1	Not yet distributed
2313013A	04-2026	1	Not yet distributed
2313014A	04-2026	1	Not yet distributed
2313015A	04-2026	1	Not yet distributed

Active Pharmaceutical Ingredient: Beclometasone Dipropionate 50 micrograms

#### Brief description of the problem

Omega Pharma Ltd. has identified that there is text missing in Section 2 of the Patient Information Leaflet (PIL) in packs of Beconase Hayfever Nasal Spray (P).

#### The current PIL states:

#### Other medicines and Beconase Hayfever

•Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines; particularly corticosteroid medicines (including eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops).

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This section is missing the following wording:

- including medicines obtained without a prescription.
- Some medicines may increase the effects of Beconase Hayfever and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

#### Advice for healthcare professionals

There is no risk to product quality as a result of this issue, and the affected batches are not being recalled. Healthcare professionals are advised to inform patients about the error when dispensing the above batches of the product or in discussion with patients who are taking other medications and to exercise caution when dispensing the above batches of the product. The batches on hold awaiting distribution will be sold and have been included in this notification for information. Omega Pharma Ltd. has confirmed that all future production batches of Beconase Hayfever Nasal Spray will contain the correct PIL.

#### **Advice for patients**

Patients should be aware that the Patient Information Leaflet (PIL) in certain batches of Beconase Hayfever Nasal Spray does not contain the most up-to-date safety information. The products themselves are not impacted and are not being recalled. Your pharmacist or other relevant healthcare professional responsible for your care can provide further information. The missing information is detailed in italics below:

Other Medicines and Beconase Hayfever

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines;
- particularly corticosteroid medicines (including eczema creams, asthma inhalers, tablets, injections, nasal sprays and eye or nose drops).
- including medicines obtained without a prescription.
- Some medicines may increase the effects of Beconase Hayfever and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

As for all medicines, if you experience any adverse reactions, you should contact your doctor immediately. You can also report suspected adverse reactions via the MHRA <u>Yellow Card scheme</u>.

#### **Further Information**

For medical information, stock control queries and Patient Information Leaflet (PIL) requests, please contact: <a href="https://doi.org/li>
<a href="https://doi.

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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