Date: 25 May 2023



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## DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Fluticasone Propionate (Flixonase) Nasule 400 micrograms (1 mg/ml) Nasal Drops Suspension: Permanent Discontinuation Notification

### Dear Healthcare Professional,

# Summary:

- Permanent discontinuation of Flixonase (fluticasone propionate) Nasule Drops due to the closure of the manufacturing site.
- Limited stock of Flixonase (fluticasone propionate) Nasule Drops will be available until December 2023.
- Flixonase (fluticasone propionate) Nasule Drops are indicated for the regular treatment of nasal polyps and associated symptoms of nasal obstruction.
- GSK recommend that healthcare professionals review patients who are currently receiving Flixonase (fluticasone propionate) Nasule Drops and discuss the prescription of an alternative treatment.

GSK in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) would like to inform you the following:

GSK is planning to discontinue Flixonase (fluticasone propionate) Nasule 400 micrograms (1 mg/ml) Nasal Drops Suspension in the UK due to the closure of its manufacturing site. GSK has notified the MHRA and the DHSC of this decision to discontinue.

To mitigate patient impact in the UK, this discontinuation has been phased. Limited stock may remain available in the market until December 2023 and pharmacies should be able to place orders through their normal wholesale routes.

We recognise that Flixonase (fluticasone propionate) Nasule Drops is an important medicine for some patients and regret any inconvenience the discontinuation may cause. Alternative products are available in the UK, so our advice to patients is to consult their healthcare professional for advice on alternative medicines.

Pack Name	EAN number	Pip Code	Discontinuation date (approx.)
Flixonase Nasule Drops	5000124440855	2618114	01/12/2023

#### Background on the safety concern

The discontinuation of Flixonase (fluticasone propionate) Nasule Drops is not related to any identified safety concern but due to the closure of the manufacturing site.

#### **Call for reporting**

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

You can report via:

- the Yellow Card website https://yellowcard.mhra.gov.uk/
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

#### **Company contact point:**

If you have any questions about this letter or require more information about Flixonase Nasule Drops, please contact a member of the GSK Medical Team.

Ms Valentina Di Boscio Head of Respiratory Medical Affairs, UK valentina.x.di-boscio@gsk.com Dr Sangeeta Sharma Medical Advisor, Classic and Established Products, UK sangeeta.8.sharma@gsk.com

For any medical queries regarding this change, please contact the GSK Medical Information Department on 0800 221 441 and select option 2, 8:30am to 5:00pm GMT, Monday to Friday, or email <u>ukmedinfo@gsk.com</u>

For any supply-related queries regarding this change, please contact GSK Customer Services on <u>customercontactuk@gsk.com</u>

Dr Mark Toms Vice President, Country Medical Director UK