19 May 2025

**Palforzia®▼ [Defatted powder of *Arachis hypogaea* L., semen (peanuts)], German stock to be supplied to the United Kingdom (UK) to mitigate supply disruption**

Dear Healthcare Professional,

To ensure continuity of supply, Stallergenes has obtained approval from the Medicines and Healthcare product Regulatory Agency (MHRA) to supply Palforzia® stock from Germany which is expected to be on the UK market between May 2025 and late July 2025.

**Summary**

Stallergenes is the sole supplier of Palforzia® [Defatted powder of Arachis hypogaea L., semen (peanuts)] to the United Kingdom.

There has been a global delay in manufacturing, and we anticipate that this will result in an out-of-stock period between May 2025 and late July 2025.

German stock of Palforzia® [Defatted powder of Arachis hypogaea L., semen (peanuts)] will be supplied to the United Kingdom to help mitigate the shortage.

Please note the following:

- This product is considered licensed in the UK.
- The product from Germany has the same formulation as the UK product.
- The product from Germany is manufactured according to the same manufacturing process and quality controls as the UK product.
- Please refer to the paper copy of the UK approved PIL supplied with the German packs. Discard the German leaflet in the pack.
- For additional copies of the leaflet, please contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Palforzia® [Defatted powder of Arachis hypogaea L., semen (peanuts)], and that the information must be given in English.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

**Background**

Palforzia® [Defatted powder of Arachis hypogaea L., semen (peanuts)] is indicated for:

- The treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy
- May be continued in patients 18 years of age and older

Please refer to the Summary of Product Characteristics for full prescribing information, available at: https://stallergenesgreer.co.uk/our-products

The out-of-stock period between May 2025 and late July 2025 will impact the following UK Presentations:

| Level (Dose) | No. of capsules for each daily dose (contained in a blister) | No. of doses in each presentation | No. of capsules in each presentation |
|---|---|---|---|
| **Level 1 (3 mg)** | 3 x 1 mg | 16 | 48 |
| **Level 2 (6 mg)** | 6 x 1 mg | 16 | 96 |
| **Level 4 (20 mg)** | 1 x 20 mg | 16 | 16 |
| **Level 5 (40 mg)** | 2 x 20 mg | 16 | 32 |
| **Level 6 (80 mg)** | 4 x 20 mg | 16 | 64 |
| **Level 7 (120 mg)** | 1 x 100 mg<br>1 x 20 mg | 16 | 32 |
| **Level 8 (160 mg)** | 1 x 100 mg<br>3 x 20 mg | 16 | 64 |

To help mitigate the shortage Stallergenes has obtained approval from the MHRA to import stock of Palforzia® from Germany.

**Information on German Presentation**

The German Palforzia® presentations look the same as the previous UK presentations (those currently available in the UK), containing both German and English languages on the Patient Information Leaflet, and the inner and outer carton. They do not contain the statement "UK Only".

A Palforzia® Patient Information Leaflet in English will be provided for each German presentation provided to the UK market.

There is no difference between the Palforzia® product contained in the German and UK presentations, and thus no change to prescribing or clinical care of your patients will be required during this temporary change in presentation being supplied.

**Call for Reporting**

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Adverse events should also be reported to Stallergenes Greer on 0800 0487217 or medinfo-eu@stallergenesgreer.com.

Palforzia® ▼ is subject to additional monitoring. This will allow quick identification of new safety information

Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle ▼ to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- 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, timing onset, treatment dates, and product brand name.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

**Stock / Ordering Queries**
For any outstanding stock related questions please contact our distribution partner Diagenics on 01908 376376 or by email info@diagenics.co.uk.

**Company Contact Point**
Should you have any questions or require additional information please contact Stallergenes Greer Medical Information on 0800 0487217 or medinfo-eu@stallergenesgreer.com.

Yours Faithfully,

Pharm Dr. Anita ČISLÁKOVÁ
Regional Medical Director NCEE-EMEA