GENUS PHARMACEUTICALS

Date: 23rd March 2026

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

**Paliperidone STADA 75mg prolonged-release suspension for injection (paliperidone)**
**Paliperidone STADA 100mg prolonged-release suspension for injection (paliperidone)**
**Paliperidone STADA 150mg prolonged-release suspension for injection (paliperidone)**
**Interim supply of foreign-language stock to mitigate Market Shortage**

Dear Healthcare Professional,

**Summary: Genus Pharmaceuticals Ltd. are temporarily supplying stock of foreign-language packs for Paliperidone prolonged-release suspension for injection (multiple strengths) in the UK (Great Britain and Northern Ireland) in response to a market shortage.**

To ensure continuity in supply to the market, Genus Pharmaceuticals Ltd. has obtained approval from the MHRA to supply product produced for European markets (France (FR) and Germany (DE)) which are expected to be on the UK (Great Britain and Northern Ireland) market from April 2026 until end-September 2026.

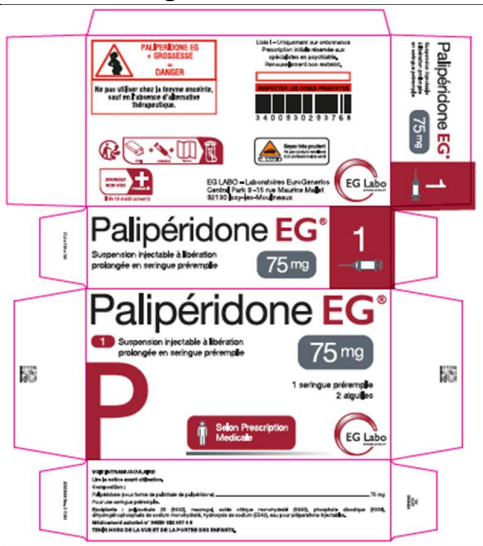
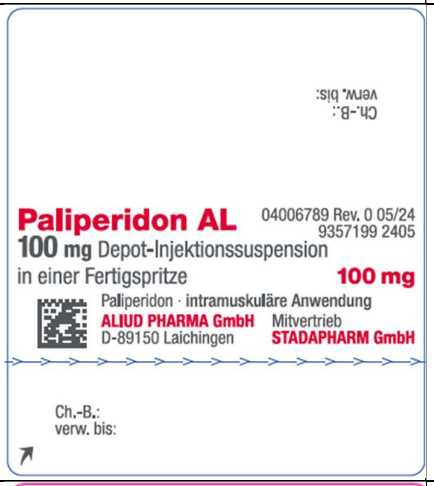
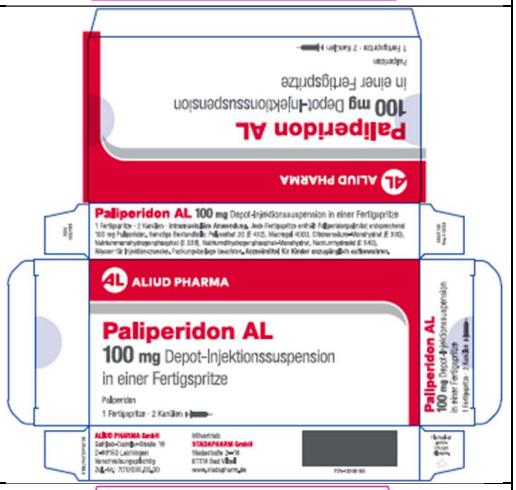
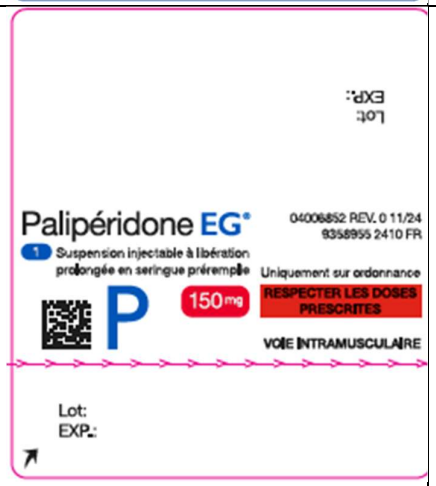
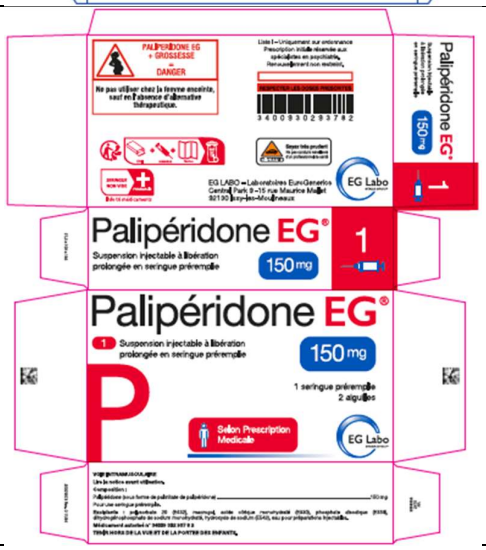
Confirmation of the source market for this stock and batch numbers/units are included below:
- Paliperidone STADA 75mg prolonged release suspension - FR – Batch # 15629CFRB - 500 units
- Paliperidone STADA 100mg prolonged release suspension - DE - Batch # 15610ADEC – 3,105 units
- Paliperidone STADA 150mg prolonged release suspension - FR - Batch # 15668AFRB - 1,400 units

Please note the following:
- These products are considered licensed in the UK
- The product produced for the French/German markets has the same formulation as the UK product
- The product produced for the French/German markets is manufactured according to the same manufacturing process and quality controls as the UK product.
- Please refer to the UK approved PIL supplied with the packs. Discard the original foreign-language leaflet in the pack.
- The UK leaflet can be found via eMC, please refer to www.medicines.org.uk/emc/product/102016 (75mg), www.medicines.org.uk/emc/product/102017 (100mg) and www.medicines.org.uk/emc/product/102018 (150mg) or 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 and Article 63.3 (Directive 2001/83/EC), from the obligation that certain particulars should appear on the outer and immediate packaging Paliperidone STADA 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.

**Please see the below table, images of the EU packs to be provided.**

GENUS PHARMACEUTICALS

| Batch details | Inner labelling | Outer Labelling |
|---|---|---|
| **75mg<br>France<br>Batch #<br>15629CFRB** |  |  |
| **100mg<br>Germany<br>Batch #<br>15610ADEC** |  |  |
| **150mg<br>France<br>Batch #<br>15668AFRB** |  |  |

| | |
|---|---|
| Genus Pharmaceuticals Ltd: Registration No. 1986459 | Genus Pharmaceuticals Ltd<br>Linthwaite, Huddersfield, HD7 5QH, United Kingdom<br>Tel: +44 (0)1484 842217<br>Fax: +44 (0)1484 847301<br>www.genuspharma.com |

**Call for reporting**
Please continue to report suspected adverse drug reactions (ADRs) 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

You can report via:

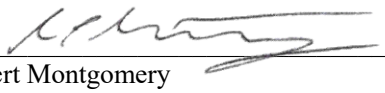
- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

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.

**Company contact point**
If you have any questions about this letter or require more information about Paliperidone STADA prolonged-release suspension for injection, please contact Thornton & Ross Ltd. Medical Information at telephone +44(0)1484 848164 or e-mail thorntonross@medinformation.co.uk.

Yours faithfully,



Robert Montgomery
Regulatory Team Leader – Licenced Medicines (NPL)
Genus Pharmaceuticals Ltd.