

Date: 01 March 2021

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

**Sublimaze[®] Solution for injection, 50 µg/ml (Fentanyl citrate):
Interim Supply of Ireland Stock to Mitigate Supply Disruption**

Dear Healthcare Professional,

Summary: Piramal Critical Care Limited, UK is currently experiencing supply disruption with Sublimaze[®] Solution for injection, 50 µg/ml (Fentanyl citrate) in the UK.

To ensure continuity in supply during the current Covid-19 situation, Piramal Critical Care Limited, UK has obtained approval from the MHRA to supply Ireland product (batch number JY7H, NL6E, 9D8R, M95M, RH5E, TA2L and SS3G 10 ml ampoules), which is expected to be on the UK market from February 2021.

Batch number	Expiry date	Quantities (no. of packs)
JY7H	31.10.2022	60
NL6E	31.03.2023	2.150
9D8R	30.04.2023	1.101
M95M	31.08.2023	2.080
RH5E	30.09.2023	21.175
TA2L	30.09.2023	19.377
SS3G	31.10.2023	24.620

Please note the following:

- This product is considered licensed in the UK.
- The product from Ireland has the same formulation as the UK product. The solution is identical in appearance.
- The product from Ireland is manufactured according to the same manufacturing process and quality controls as the UK product.
- The leaflet provided with the Ireland packs should be discarded and replaced with a copy of the UK leaflet as the UK leaflet contains information that is not in the Ireland leaflet.
- Copies of the UK leaflet can be downloaded from the website <https://www.medicines.org.uk/emc/> or if you prefer, contact the company contact point (see below).
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.
- The DHPC document will be distributed with each delivery via commercial database like DMD, uploaded on the NHS website and will be provided to PHE to distribute through their internal system

Piramal Critical Care Limited

(Formerly Piramal Life Sciences (UK) Limited)

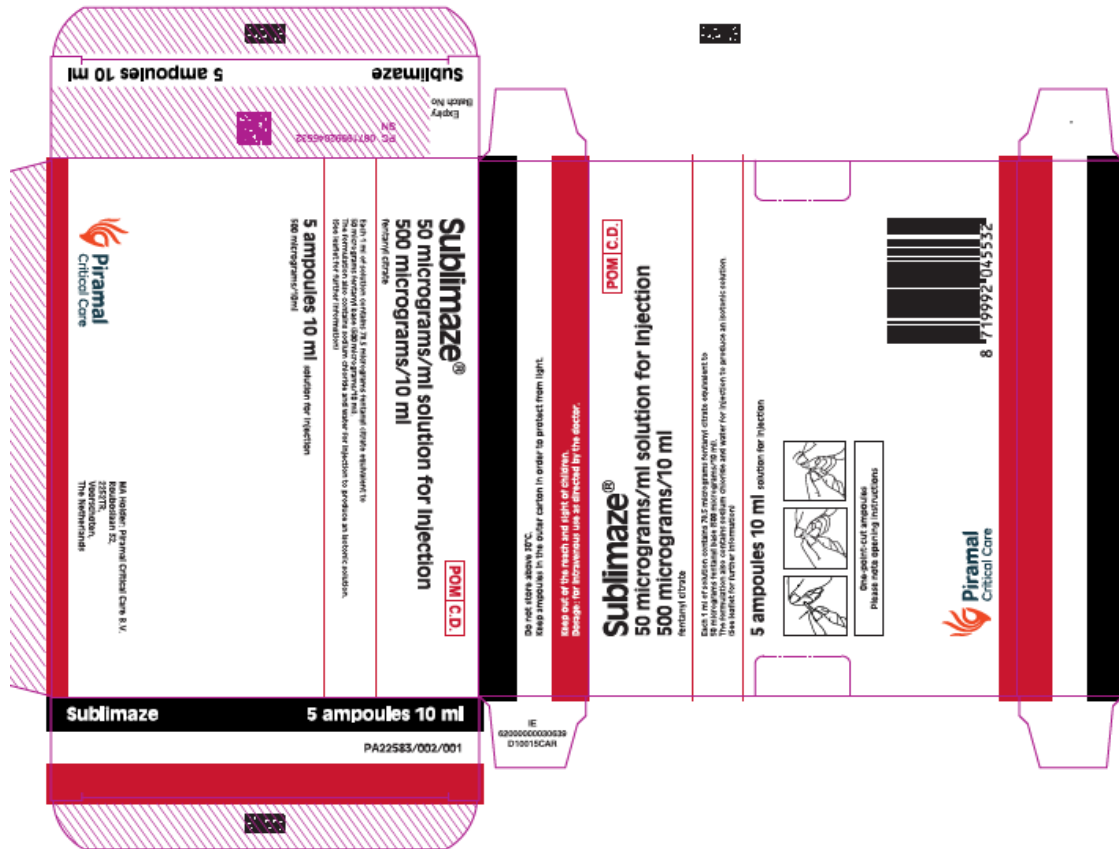
Registered Office : Suite 4, Ground Floor, Heathrow Boulevard - East Wing, 280 Bath Road, West Drayton
United Kingdom - UB7 0DQ

Tel: 020875 93411

W www.piramal.com/criticalcare

Company Registration No : 5160306

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



Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://www.gov.uk/yellowcard>, the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#), and some clinical IT systems (EMIS,

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SystemOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

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

Company contact point

If you have any questions about this letter or wish more information about **Sublimaze® Solution for injection, 50 µg/ml (Fentanyl citrate)**, please contact Piramal Critical Care Limited, UK on is +44(0)800-756-3979 or Medical.Information@piramal.com.

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