THIS INFORMATION IS CONFIDENTIAL TO THE NHS AS IT MAY BE COMMERCIALLY SENSITIVE

Covid-19 - Quality Assessment – Unlicensed Imported Medicine

Lorazepam 2mg per mL single dose Carpuject™ Hospira

Assessment date	Assessment issue	Assessed by
29/4/20	1	NWPQA

Product information

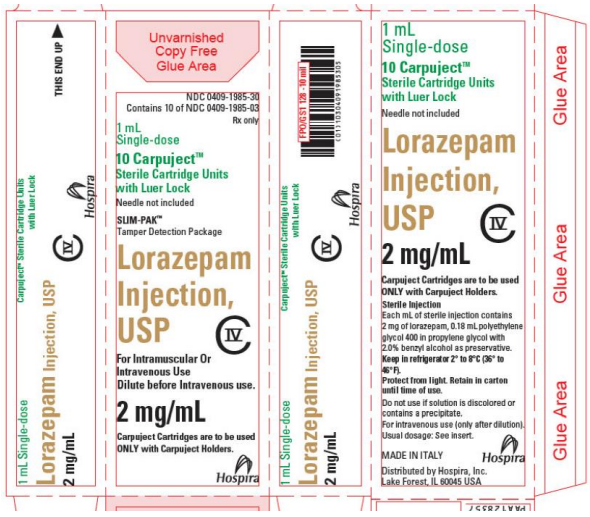
Licence/MA holder:	Manufacturer
Hospira (Pfizer) USA	Hospira (Pfizer) USA
MA number (equivalent):	**Licensed in:**
ANDA074243 NDC 0409-1539-31	USA
Active Ingredient(s)	**Other Ingredient(s)**
Lorazepam	Polyethylene glycol 400 Propylene glycol Benzyl alcohol (2%)
Licensed Route(s)	**Latex Status**
Intravenous Intramuscular	Not known
Summary of Product Characteristics	**Patient Information Leaflet**
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=20140b19-846b-425f-b191-670e17809945	Not available

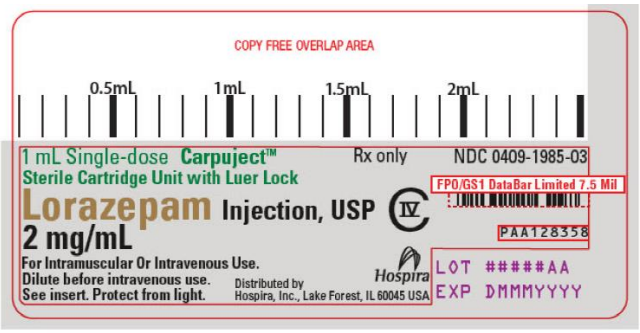
Storage conditions

2 to 8°C
Protect from light

Product Images

Artwork files:





Photos:

Cartridge

Holder

Pharmaceutical Quality Assessment	
MHRA non-objection to import	TSE certification
Received	Not applicable – Relevant Mutual Recognition Agreement in place between EU and USA

Evidence of manufacturer's compliance with the principles of Good Manufacturing Practice (Directive 2003/94/EC)

Product is manufactured in USA, with the active pharmaceutical ingredient (API) made in Italy as stated on the pack. It is licensed in a country with which the EU has a relevant Mutual Recognition Agreement, therefore compliance with standards equivalent to GMP is assured.

Packaging and Labelling Assessment

- Presentation is a 1mL single dose Carpuject™ sterile cartridge unit with luer lock to be uses in combination with Carpuject™ holder device. This type of device has not been used in the UK and has potential to cause confusion
- Product is named and labelled Lorazepam Injection, USP 2mg/mL which is a different strength than the UK licensed Ativan (Lorazepam 4mg/mL)
- Otherwise the product is clearly labelled and overlabelling is not required.

Additional information

- This medicine is being imported by Pfizer owing to the shortage of their contracted product. Pfizer have prepared an information letter for healthcare professionals which will be supplied with the product
- A Carpuject™ holder device will be provided with each cartridge for single delivery/dosing
- Carpuject™ cartridges must not be used as multiple dose containers

Comments and Recommendations to Trusts

- Ensure all Healthcare Professionals involved in the administration of lorazepam solution for injection are familiar with the details and the process for administering the Carpuject™ presentation of this medicine
- Ensure prescribers and users are aware that the product is Lorazepam 2mg/mL which is different to the UK licensed Ativan (4mg/mL)
- Ensure users are provided with a copy of the drug information leaflet
- Follow usual unlicensed medicines policy for recording receipt and use of unlicensed medicines.