



Worldwide Biopharmaceutical Businesses

Date: 01 May 2020

INFORMATION FOR HEALTHCARE PROFESSIONALS

To: Healthcare Professionals

Re: Temporary supply of a different presentation and changes to the instructions for Ativan 4mg/ml Solution for Injection (Lorazepam) (PL 00057/1279)

Due to supply disruption we are temporarily managing the supply of Ativan (Lorazepam) 4mg/ml from early May 2020 with alternative US product – LORAZEPAM injection, solution 2mg/ml pre-filled cartridges.

As the presentation of Ativan being supplied on a temporary basis will be unfamiliar to UK Healthcare Professionals (HCPs), please read the following information carefully and ensure all HCPs involved in the administration of lorazepam solution for injection are familiar with the details and the process for administering the medicine.

A summary of the key points are as follows:

- To help mitigate the national shortfall in supply against demand, Pfizer has obtained agreement for an Unlicensed Medicinal Import application from the Medicines and Healthcare products Regulatory Agency (MHRA) to import Pfizer stock of LORAZEPAM injection, solution 2mg/ml from the US
- The constituents/excipients of UK and US formulations are identical and the benefit-risk profile is consistent with the UK formulation, however please note the different concentration/total dose (UK Ativan vials: each ampoule contains 1ml of **4mg/ml** solution for a full dose of **4mg**; US LORAZEPAM injection: Each cartridge contains 1ml of **2mg/ml** solution for a full dose of **2mg**)
- US pre-filled cartridges of lorazepam solution 2mg/ml are considered an unlicensed product in the UK
- See table for differences in presentation, dilution and preparation between products
- US lorazepam solution 2mg/ml is supplied in Carpuject™ Single-dose cartridges with Luer Lock. Carpuject™ holders will be provided to allow for delivery/dosing. Carpuject should be used only to deliver Lorazepam Injection USP 2 mg/mL during the supply shortage
- Please note the expiry of the US lorazepam solution 2mg/ml is January 1st 2021

The UK Summary of Product Characteristics and Patient Information Leaflet for Ativan 4mg/ml Solution for Injection (Lorazepam) can be found at: <https://www.medicines.org.uk/emc/product/5473>

The US Summary of Product Characteristics and Patient Information Leaflet for LORAZEPAM injection, solution 2mg/ml can be found at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=20140b19-846b-425f-b191-670e17809945>

Instructions on the use of the Carpuject™ cartridges and holder can be found at: <https://www.pfizerpro.com/product/readytouse> (video). A printed user guide is also included with this letter and will be available with all supplies.

DIFFERENCES IN PRESENTATION:

For your awareness the key differences between Ativan 4mg/ml Solution for Injection (Lorazepam) (PL 00057/1279) and LORAZEPAM injection, solution 2mg/ml product have been highlighted in the table below.

Table 1. Notable differences between the US and UK product

Distributed by	Hospira Inc USA	Pfizer Ltd UK
Product Name	LORAZEPAM injection, solution 2mg/ml	Ativan 4mg/ml Solution for Injection (Lorazepam)
Licensed Indication	Status Epilepticus: Lorazepam Injection is indicated for the treatment of status epilepticus. Preanesthetic: Lorazepam injection is indicated in adult patients for preanesthetic medication, producing sedation (sleepiness or drowsiness), relief of anxiety, and a decreased ability to recall events related to the day of surgery. It is most useful in those patients who are anxious about their surgical procedure and who would prefer to have diminished recall of the events of the day of surgery	Pre-operative medication or premedication for uncomfortable or prolonged investigations, e.g. bronchoscopy, arteriography, endoscopy. The treatment of acute anxiety states, acute excitement or acute mania. The control of status epilepticus.
Solution strength/dose	Each cartridge contains 1ml of 2mg/ml solution for a full dose of 2mg	Each ampoule contains 1ml of 4mg/ml solution for a full dose of 4mg
Primary Container	Carpject™, Single-dose cartridge with Luer Lock for the Carpuject™ Syringe System	2ml ampoules (Type I glass) with a one-point-cut opening
No. of Packs	10 cartridges of 1ml; Each cartridge contains 1ml of solution for injection	10 ampoules of 1ml; Each ampoule contains 1ml of solution for injection
Administration	Carpject™ cartridges must be used in combination with the Carpuject™ holder for dilution/administration of the solution Intramuscular administration: When given intramuscularly, Lorazepam Injection, undiluted, should be injected deep in the muscle mass.	Ativan solution can be diluted and/or withdrawn directly from the ampoule Intramuscular administration: A 1:1 dilution of Ativan Injection with normal saline or Sterile Water for Injection BP is recommended in order to facilitate intramuscular administration.

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, 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.

Further Information

LORAZEPAM injection, solution 2mg/ml which is the alternative to Ativan 4mg/ml Solution for Injection (Lorazepam) can be ordered through the new PIP code **8140907** via Alliance Healthcare.
Lot Number: 01600LL.

LORAZEPAM injection, solution 2mg/ml orders are provided with compatible Carpuject™ holders. The holders are designed to be reusable, however we recognize that this may not be feasible where additional cautions are in place due to coronavirus mitigation practices.

Please note expiry of the LORAZEPAM injection, solution 2mg/ml is January 1st 2021.

If you have any questions about this letter, please contact Pfizer Medical Information at the following address:

Medical Information, Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey KT20 7NS. United Kingdom. Telephone: **01304 616161** or visit <https://www.pfizermedicalinformation.co.uk/>

For questions concerning the supply and order quantities of Lorazepam injection, please contact the Pfizer Customer Contact Centre on **0845 608 8866**.

The supply of US LORAZEPAM injection is being implemented in order to mitigate stock shortages brought about by supply disruption to the licensed UK Ativan 4mg/ml Solution for Injection (Lorazepam). It is hoped that approved UK Ativan stock will be available for order again during June, although this is still to be confirmed.

Kind regards,



Greg Coates
Medical Affairs, Internal Medicine, Pfizer Ltd