



Worldwide Biopharmaceutical Businesses

Date: 11 May 2020

INFORMATION FOR HEALTHCARE PROFESSIONALS

To: Healthcare Professionals

Re: Temporary supply of a different presentation in market and changes to the instructions for pancuronium bromide 2mg/ml Solution for Injection (PL 04515/0062)

Due to supply disruption we are temporarily managing the supply of pancuronium bromide **2mg/ml** with an alternative US product – PANCURONIUM BROMIDE injection USP 10mg/10ml (**1mg/ml**) multiple-dose fliptop glass vials¹.

As the presentation of pancuronium being supplied on a temporary basis will be unfamiliar to UK healthcare professionals (HCPs), please read the following information carefully and ensure that all HCPs involved in the administration of pancuronium bromide are familiar with the details, including the strength and excipients of 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 Medicine Import application from the Medicines and Healthcare products Regulatory Agency (MHRA) to import Pfizer stock of PANCURONIUM BROMIDE 10mg/10ml injection from the US
- The solution strength is different:
 - UK – each ampoule contains 4mg/2ml of pancuronium bromide (**2mg/ml**)
 - US – each multiple-dose fliptop vial contains 10mg/10ml of pancuronium bromide (**1mg/ml**)
- US pancuronium bromide contains benzyl alcohol as preservative (10mg/ml) and exposure to excessive amounts of benzyl alcohol has been associated with toxicity (hypotension, metabolic acidosis), particularly in neonates
- US multiple-dose fliptop vials 10mg/10ml are an unlicensed product in the UK
- See table 1 for key differences in presentation, excipients and warnings
- Please note expiry of the US PANCURONIUM BROMIDE 10mg/10ml is 1 July 2020

¹ USP - United States Pharmacopeia

The UK Summary of Product Characteristics and Patient Information Leaflet for Pancuronium Bromide 2 mg/ml Solution for Injection can be found at:

<https://www.medicines.org.uk/emc/product/3793>

The US Prescribing Information for Pancuronium Bromide Injection can be found at:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d705382b-8aa0-4893-ed9e-bcf7c7d9d0a2>

DIFFERENCES IN PRESENTATION:

For your awareness the key differences between the UK pancuronium bromide 2 mg/ml (PL04515/0062) and the US Pancuronium Bromide 10 mg/10 ml product have been highlighted in the table below.

Table 1. Notable differences between the US and UK product

Distributed by	Hospira Inc USA	Hospira Ltd UK
Product	Pancuronium Bromide Injection, USP 10 mg/10 mL (1 mg/mL) ¹	Pancuronium Bromide 2 mg/ml Solution for Injection
Strength	10 mg/10 mL (1 mg/mL)	2 mg/ml
Primary Container	Multiple-dose fliptop glass vials	Glass ampoules.
Excipients	1ml contains Sodium acetate, anhydrous 1.2 mg; Benzyl alcohol 10 mg as preservative Sodium chloride added to adjust tonicity May contain acetic acid and/or sodium hydroxide for pH adjustment	Sodium chloride Sodium acetate Water for injections
Storage Conditions	Store in refrigerator 2° to 8°C	Store in a refrigerator 2°C to 8°C Do not freeze. Keep the ampoule in the outer carton in order to protect from light.
Warning	Contains benzyl alcohol, exposure to excessive amounts of benzyl alcohol has been associated with toxicity (hypotension, metabolic acidosis), particularly in neonates	Does not contain benzyl alcohol

¹ USP - United States Pharmacopeia

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

Pancuronium bromide 10mg/10ml SSOL 1X25 FTV which is the alternative to Pancuronium bromide 4mg/2ml can be ordered via the Pfizer Customer Contact Centre. To place your order or if you have any queries relating to this product please call the Pfizer Customer Contact Centre on 0845 608 8866 and use PIP code **816-9153**

Please note expiry of the PANCURONIUM BROMIDE 10mg/10ml is 1 July 2020.

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/>

Kind regards

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