Pfizer Limited
Walton Oaks, Dorking Road,
Tadworth, Surrey,
KT20 7NS, UK
Telephone: +44 (0) 1304 616161

24th February 2022

Direct Healthcare Professional Communication

Dear Healthcare Professional,

Prostin VR Pediatric® (alprostadil 500 micrograms/ml Concentrate for solution for infusion) – Temporary supply of unlicensed imported product from the USA

Summary:

There is out of stock situation of Prostin VR 500 micrograms/ml Concentrate for solution for infusion (PL 00057/1031) due to a delay in manufacturing.

To ensure continuity in supply, Pfizer Ltd has obtained agreement from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply Prostin VR Pediatric (alprostadil 500 micrograms/ml Concentrate for solution for infusion) from the US. Batch number FM2278. Expiry date: 29th Feb 2024.

- The US Prostin VR alprostadil product has the same formulation as the UK licensed product; a comparison of the two products is shown in the table on page 2.

- The number of packs to be imported is 96 (5 x 1ml ampoules), which is equivalent to 9 weeks of supply to the UK.

- The US product is unlicensed in the UK. This means that the imported product has not been given a Marketing Authorisation by the MHRA.

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

Background to safety issue
The UK product Prostin VR 500 micrograms/ml Concentrate for solution for infusion is indicated to temporarily maintain the patency of the ductus arteriosus until corrective or palliative surgery can be performed in infants who have congenital defects and who depend upon the patent ductus for survival. Such congenital heart defects include pulmonary atresia, pulmonary stenosis, tricuspid atresia, tetralogy of Fallot, interruption of the aortic arch, co-arctation of the aorta, aortic stenosis, aortic atresia, mitral atresia, or transposition of the great vessels with or without other defects.

Due to a manufacturing issue, Prostin VR 500 micrograms/ml Concentrate for solution for infusion (PL 00057/1031) has been out of stock in the UK since 11th February 2022. Resupply is expected by 25th February 2022. The US stock may still be used after this date until UK supply of alprostadil stabilises.

To help mitigate the shortage we have obtained for supply to the UK a batch of unlicenced Prostin VR Pediatric alprostadil injection, USP 500 micrograms per mL (from the USA).

Key aspects of the UK licensed product and US unlicensed product are detailed below.

	Prostin VR® (alprostadil) 500 micrograms/ml Concentrate for solution for infusion 500 micrograms/1ml ampoules (UK)	**Prostin VR Pediatric® alprostadil injection, USP 500 micrograms per mL (USA)**
Pack Size	5x1ml ampoules	5x1ml ampoules
Appearance	Concentrate for solution for infusion (Sterile concentrate). Clear, colourless solution	Sterile Solution for intravascular infusion
Excipients (per vial)	Each 1 ml vial of Prostin VR® contains 790 mg anhydrous ethanol	1.0 mL dehydrated alcohol.
Packaging information	1ml Type I clear glass ampoule. Multipacks containing 5 x 1 ml ampoules	5 ×1 mL ampoules
Storage	Store in a refrigerator Special precautions for disposal and other handling Dilution instructions To prepare infusion solutions, dilute 1 ml of Prostin VR® with sterile 0.9% sodium chloride intravenous infusion or sterile 5% dextrose intravenous infusion. If undiluted Prostin VR® comes in direct contact with a plastic container, plasticisers are leached from the side walls. The solution may turn hazy and the appearance of the container may	Store PROSTIN VR PEDIATRIC® Sterile Solution in a refrigerator at 2° to 8°C (36° to 46°F). To prepare infusion solutions, dilute 1 mL of PROSTIN VR PEDIATRIC® Sterile Solution with Sodium Chloride Injection USP or Dextrose Injection USP. Undiluted PROSTIN VR PEDIATRIC® Sterile Solution may interact with the plastic sidewalls of volumetric infusion chambers causing a change in the appearance of the chamber and creating a hazy solution.

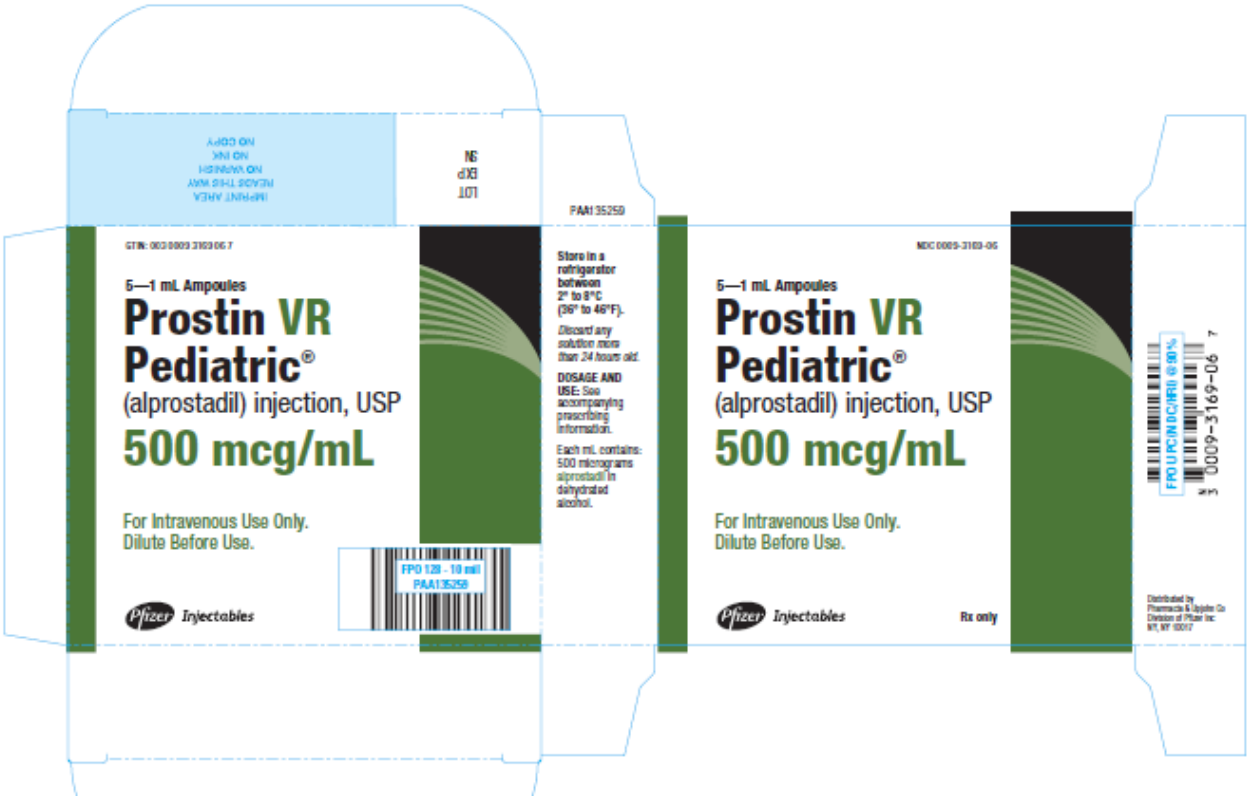
	change. Should this occur, the solution should be discarded and the plastic container should be replaced. This appears to be a concentration-dependent phenomenon. To minimise the possibility of haze formation, Prostin VR® should be added directly to the intravenous infusion solution, avoiding contact with the walls of plastic containers. Dilute to volumes appropriate for the delivery system available. Prepare fresh infusion solutions every 24 hours. Discard any solution more than 24 hours old.	Should this occur, the solution and the volumetric infusion chamber should be replaced. When using a volumetric infusion chamber, the appropriate amount of intravenous infusion solution should be added to the chamber first. The undiluted PROSTIN VR PEDIATRIC® Sterile Solution should then be added to the intravenous infusion solution, avoiding direct contact of the undiluted solution with the walls of the volumetric infusion chamber. Dilute to volumes appropriate for the pump delivery system available. Prepare fresh infusion solutions every 24 hours. Discard any solution more than 24 hours old

The UK Summary of Product Characteristics and Patient Information Leaflet for Prostin VR® 500 micrograms/ml Concentrate for solution for infusion can be found at: https://www.medicines.org.uk/emc/product/1092

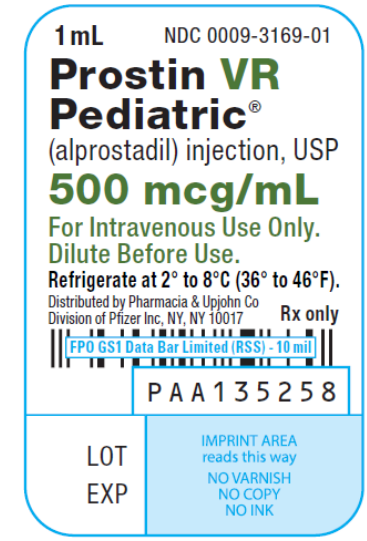
<u>US batch and packaging information for Prostin VR Pediatric®:</u>

Batch: FM2278.
Expiry date: 29th Feb 2024

CARTON:



LABEL:



Call for reporting of suspected adverse reactions:

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://yellowcard.mhra.gov.uk/, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects 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 timing, treatment dates, and product brand name.

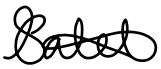
Further Information:

Contact Pfizer Customer Service on **0345 608 8866** who will manage your order.

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/

Yours faithfully,



Seema Patel
Northern Europe Medical Lead
Pfizer Hospital Medicines