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DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Hemabate® Sterile Solution (carboprost tromethamine 250 mcg/mL ampoules), PL 00057/1000: Temporary supply of Carboprost Tromethamine 250mcg/ml Injection, USP to mitigate supply disruption

Dear Healthcare Professional,

Pfizer Limited in agreement with Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Due to supply disruption, we are temporarily managing the supply of Hemabate Sterile Solution (carboprost tromethamine 250 mcg/mL ampoules), PL 00057/1000, with an unlicensed medicinal product imported from the USA: Carboprost Tromethamine (250 mcg/mL) injection, USP[1]. Around 250 packs of the USA product will be distributed, these should cover the shortage of the UK product until its expected replenishment at the beginning of May 2025.

Summary:

- The USA product is unlicensed in the UK; this means that the imported product has not been given a Marketing Authorisation license by the MHRA, it only has a license from the USA FDA;
- The USA product has additional indications which are not approved in the UK. **The product in the UK should only be used for the treatment of post-partum haemorrhage due to uterine atony and refractory to conventional methods of treatment with oxytocic agents and ergometrine used either alone or in combination. It should only be administered via the intramuscular route**.
- The USA product is a generic version of the UK branded product, with the exact same formulation;
- The main differences between the two products are in the product particulars: SmPC, PIL, labelling and primary packaging. In the USA, the product comes in vials, while in the UK, it comes in ampoules;
- **Hemabate should be administered as an intramuscular injection**. The UK product information contains a warning statement: "Hemabate must not be given intravenously", which is absent in the USA product information and product labelling. Nevertheless, the imported USA product should be administered in the same way as the UK licensed product, which is via the intramuscular route.
- Hemabate is contraindicated in pregnancy in the UK.

[1] USP - United States Pharmacopeia

As the USA product (being supplied on a temporary basis) will be unfamiliar to UK Healthcare Professionals, please ensure that all HCPs involved in the prescribing, supply and administration of Carboprost Tromethamine are familiar with the details. This should include the IM route of administration and the approved UK indication.

The indication for the licensed UK product Hemabate® Sterile Solution (carboprost tromethamine), PL 00057/1000 is treatment of post-partum haemorrhage due to uterine atony and refractory to conventional methods of treatment with oxytocic agents and ergometrine used either alone or in combination.

For ease of reference, please see a representation of the UK authorised pack and the imported USA pack in comparison below:

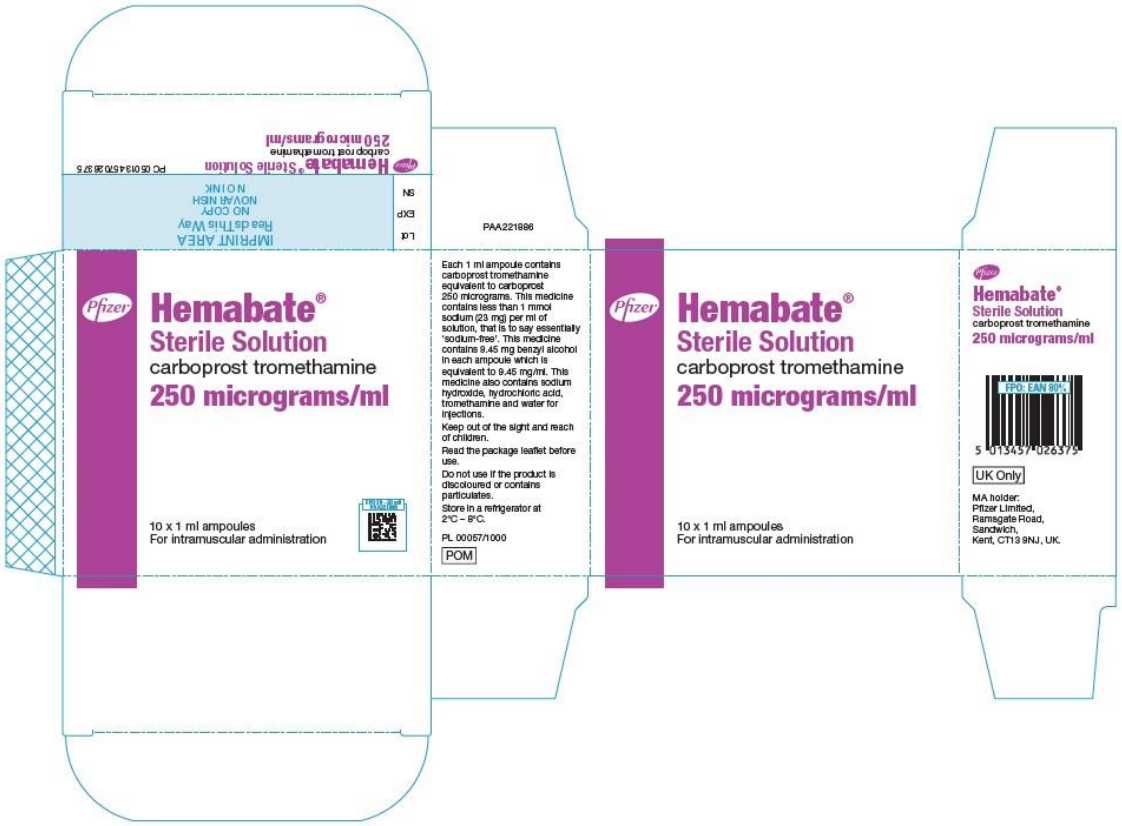

Fig 1: Licensed UK product labelling - Hemabate Sterile Solution (Carboprost tromethamine 250 mcg/mL ampoules), PL 00057/1000

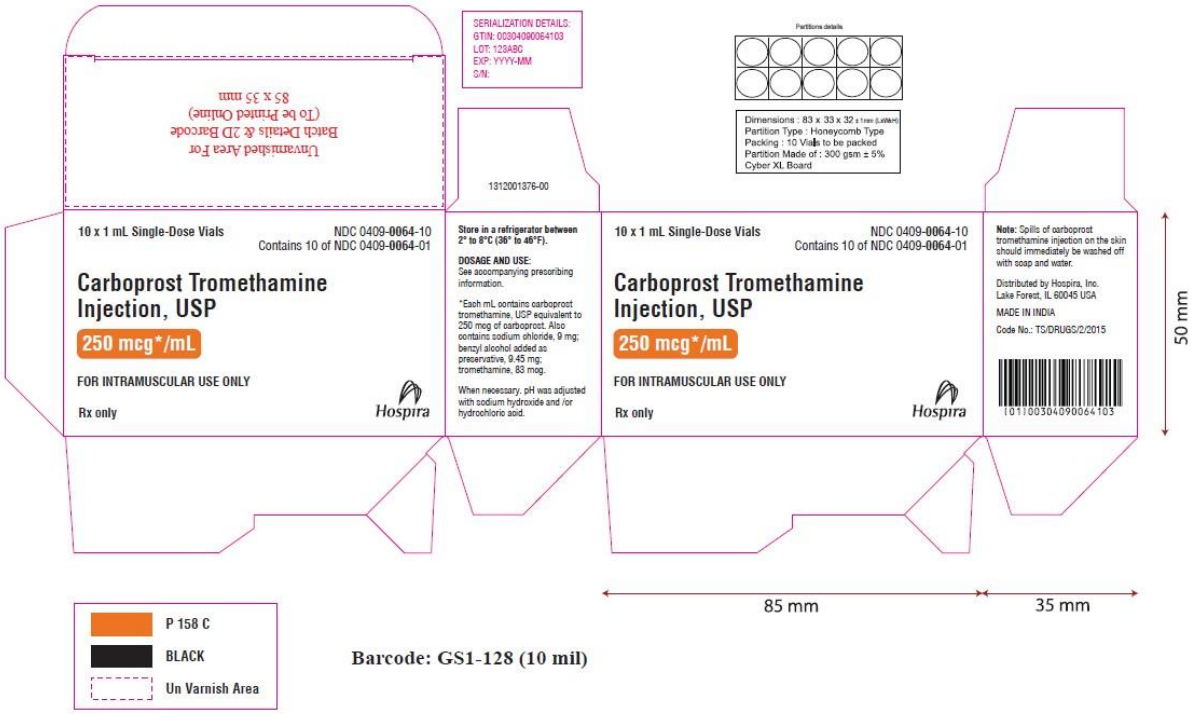

Fig. 2: Imported US product labelling - Carboprost Tromethamine (250 mcg/mL) injection, USP

The UK Summary of Product Characteristics and Patient Information Leaflet for Hemabate Sterile Solution (Carboprost tromethamine), PL 00057/1000 can be found at: https://www.medicines.org.uk/emc/product/1084 (SmPC)

https://www.medicines.org.uk/emc/files/pil.1084.pdf (PIL)

The US Prescribing Information for Carboprost Tromethamine injection, USP can be found at: https://labeling.pfizer.com/ShowLabeling.aspx?id=20577

Call for Reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Further Information

If you have any questions about this letter or for more information about Hemabate, please contact Pfizer Medical Information at www.pfizermedicalinformation.co.uk, Telephone: 01304 616161 or Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.

Yours sincerely,

Seema Patel

Specialty Care Medical Director

Pfizer UK