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Date: 18 August 2021

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

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

Dear Healthcare Professional,

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: Hemabate carboprost tromethamine (250 mcg/mL) injection, USP[1]. Around 700 packs of the US product will be distributed, these should cover the shortage of the UK product until its expected replenishment at the beginning of September 2021.

Summary:

- To assist in maintaining continuity in the supply of this product, Pfizer has obtained agreement from the Medicines and Healthcare products Regulatory Agency (MHRA) to import unlicensed stock of Hemabate carboprost tromethamine injection, USP[1] from the USA;
- The US product is unlicensed in the UK; this means that the imported product hasn't been given a Marketing Authorisation license by the MHRA, it only has a license from the US FDA;
- The US product has the exact same formulation as the UK licenced product;
- The main differences between the two products are in the product particulars: SmPC, PIL and labelling;
- **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 US product information and product labelling. Nevertheless, the imported US product should be administered in the same way as the UK licensed product, which is via the intramuscular route;
- Due to the difference in product licence, the US 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**;
- Hemabate is contraindicated in pregnancy in the UK.

[1] USP - United States Pharmacopeia

As the US product (being supplied on a temporary basis) will be unfamiliar to UK Healthcare Professionals, please ensure that all HCPs involved in the 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 US pack in comparison below:

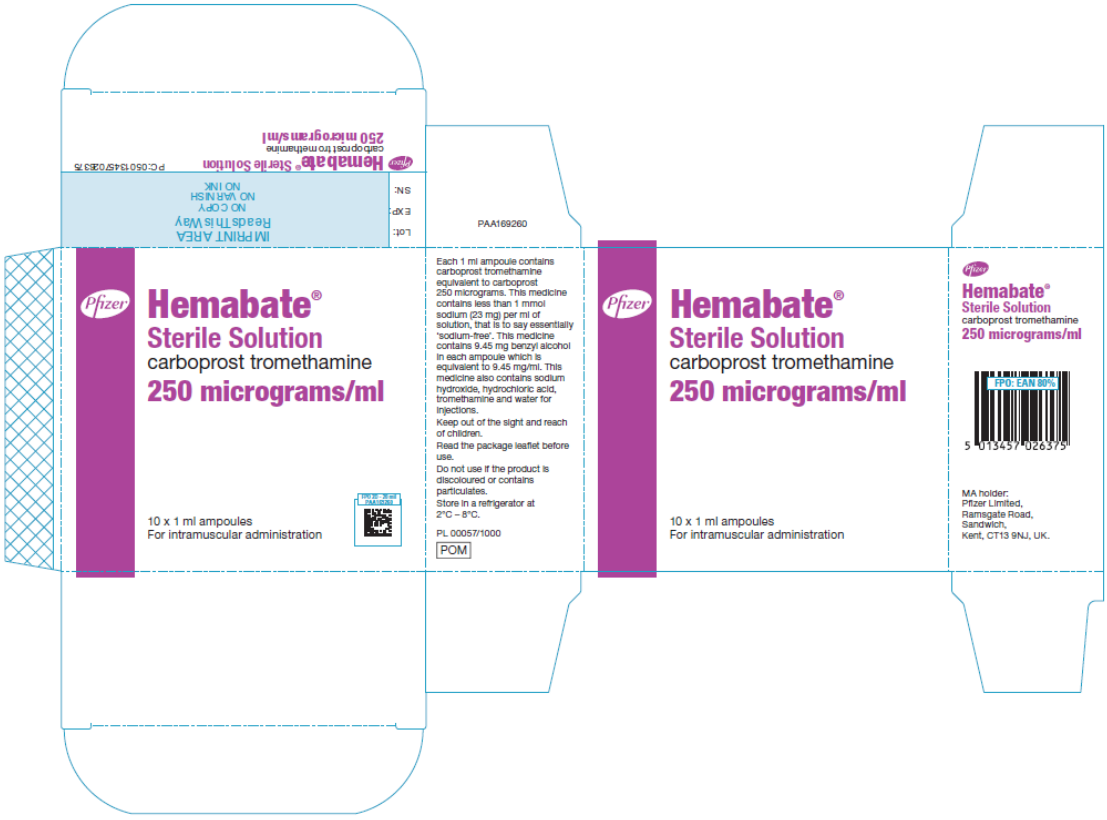


Fig 1: Licensed UK product labelling - Hemabate Sterile Solution (Carboprost tromethamine 250 mcg/mL ampoules), PL 00057/1000

Fig. 2: Imported US product labelling - Hemabate 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 Hemabate carboprost tromethamine injection, USP can be found at:

labeling.pfizer.com/ShowLabeling.aspx?id=598

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, SystmOne, Vision, MiDatabank) for Healthcare Professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

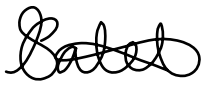
When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates and product brand name.

Further Information

If you have any queries relating to this product please call the Pfizer Customer Contact Centre on 0845 608 8866 and use PIP code **8033441.**

If you have any questions about this letter, please contact Pfizer Medical Information on **01304 616161** or visit https://www.pfizermedicalinformation.co.uk/

Yours sincerely,



Seema Patel

Northern Europe Medical Lead
Pfizer Hospital Medicines