



Supply of Licensed and Unlicensed Epidural Infusion Bags

Date of issue:	23-Jan-23	Reference no:	NatPSA/2023/002/CMU
This alert is for action by: acute care hospitals, and any other organisations providing procedures that require epidural infusions.			
This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in pharmacy, theatres, anaesthesia and critical care, a Medicine Safety Officer (MSO) and Medicine Device Safety Officer (MDSO).			

Explanation of identified safety issue:

There are supply issues impacting Fresenius Kabi (FK) unlicensed epidural bags containing bupivacaine only and levobupivacaine with fentanyl. These are also impacting Sintetica's licensed epidural bags containing bupivacaine only and bupivacaine with fentanyl (see Additional Information).

A range of alternative licensed and unlicensed bags is available during the affected period (see Additional Information), but the use of these products will require a co-ordinated trust wide approach to ensure safe implementation.

Preparing epidural infusions in clinical areas using individual components poses a significant patient safety risk from calculation, measurement and preparation errors, resulting in incorrect dosing, and from microbial contamination. Preparation in clinical areas should only be considered if all other options have been exhausted.

To mitigate and manage patient safety risks, trusts should use alternative pre-prepared (licensed or unlicensed) epidural infusion bags as first line options.

FK should have new stock available week commencing 30 January 2023, pending QA approval.
Sintetica products should be available from mid-late February 2023.

Actions required



Actions to be completed by 27/01/2023

1. Review products in use and current stock holding, to establish the impact of the supply shortage.
2. Where necessary, agree a trust-wide action plan to temporarily use alternative product(s) (see Additional Information) taking into consideration the need to:
 - a. review and update local guidelines, protocols, epidural charts and/or ePrescribing order sets to reflect agreed changes at trust level;
 - b. work with trust MSO/MDSO to review the infusion pumps used and whether there is a need to change drug library settings where alternative products are utilised; and
 - c. review products already being made in pharmacy aseptic units to release capacity if necessary.
3. If the products listed in the table below are not considered appropriate, seek advice from lead anaesthetist on alternative management options, such as epidural bolus administration, regional blocks and patient-controlled analgesia.
4. If actions 2 and 3 are deemed unsuitable, a decision to prepare alternative infusions in-house must include a comprehensive risk assessment noting that:
 - a. Preparing infusions in pharmacy aseptic facilities should be considered as first line choice
 - b. Preparing epidural infusions in clinical areas poses a significant safety risk and should only be undertaken if:
 - All other options have been exhausted;
 - The risk assessment has been approved by Chief Pharmacist and Medical Director, and subsequently reported through a board-reporting committee.

All epidural infusions prepared in pharmacy, or in clinical areas, must be clearly labelled as per guidance – see [Enduring standards and general principles from previously issued patient safety alerts: Medication labelling](#).

Additional information:

Epidural Infusion Bags now out of stock

Sintetica (licensed) products

Bupivacaine 250mg/250ml (0.1%) / Fentanyl 500micrograms/250ml infusion bags
Bupivacaine 250mg/250ml (0.1%) infusion bags
Bupivacaine 312.5mg/250ml (0.125%) infusion bags

Fresenius Kabi (unlicensed) products

Levobupivacaine 250mg/250ml / Fentanyl 1.25mg/250ml infusion bags
Levobupivacaine 250mg/250ml / Fentanyl 500micrograms/250ml infusion bags
Levobupivacaine 500mg/500ml / Fentanyl 1mg/500ml infusion bags
Levobupivacaine 500mg/500ml / Fentanyl 2mg/500ml infusion bags
Levobupivacaine hydrochloride 625mg/500ml / Fentanyl 2mg/500ml infusion bags
Levobupivacaine 100mg/100ml / Fentanyl 200micrograms/100ml infusion bags
Levobupivacaine 125mg/100ml / Fentanyl 200micrograms/100ml infusion bags

Stock currently available now

Sintetica (licensed) epidural infusions available to order now from Mawdsley's

Bupivacaine 312.5mg/250ml (0.125%) / Fentanyl 500micrograms/250ml infusion bags
Bupivacaine 625mg/500ml (0.125%) / Fentanyl 1mg/500ml infusion bags

Limited stock of

Bupivacaine 500mg/500ml (0.1%) / Fentanyl 1mg/500ml infusion bags

Fresenius Kabi (unlicensed) epidural infusions available to order now directly from Fresenius Kabi

Bupivacaine 500mg/500ml (0.1%) / Fentanyl 1mg/500ml infusion bags

Limited stock of

Bupivacaine 750mg/500ml (0.15%) infusion bags
Bupivacaine 250mg/250ml (0.1%) / Fentanyl 500micrograms/250ml infusion bags
Bupivacaine 100mg/100ml (0.1%) / Fentanyl 200micrograms/100ml infusion bags
Bupivacaine 625mg/500ml (0.125%) / Fentanyl 1mg/500ml infusion bags
Levobupivacaine hydrochloride 625mg/500ml / Fentanyl 1mg/500ml infusion bags

Fresenius Kabi (licensed) epidural infusions available to order now directly from Fresenius Kabi

Levobupivacaine 125mg/100ml infusion bags

Ethylpharm (licensed) epidural infusions available to order now from Alliance and Mawdsley's

Levobupivacaine 250mg/200ml infusion bags (licensed)

Guidance on ordering and prescribing unlicensed medicines

Any decision to prescribe an unlicensed medicine must be supported by relevant guidance and local medicines governance policy and procedures. Please see the links below for further information:

- [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
- [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
- [Prescribing unlicensed medicines](#), General Medical Council (GMC),

Stakeholder engagement

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Service, national Medicines Shortage Response Group, NHS England National Clinical Directors for Critical and Perioperative Care.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to [CHT/2019/001](#) your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.