Department of Health & Social Care

Supply Disruption Alert

SDA/2019/003 Issued: 04 July 2019 at 11:00 Valid until: 22 July 2019

Marcain Heavy 0.5% Solution for Injection – Supply Disruption

Summary

- Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection will be out of stock until 22nd July.
- Marcain Heavy 0.5% solution for injection is indicated in adults and children of all ages for intrathecal (subarachnoid) spinal anaesthesia for surgery including caesarean section.
- The following management plan has been developed in collaboration with NHS England, the Royal College of Anaesthetists (RCoA) and the Association of Anaesthetists.
- Further work is ongoing with these organisations to consider implications of this supply issue and guidance advising about further alternative options will be shared through clinical networks if necessary.
- Other bupivacaine injectable preparations continue to remain available during this time.

Action

- Centralise stock of Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection from all clinical areas except obstetrics with support from pharmacy.
- Local decisions should be made about which clinical areas/specialties can safely use alternatives to Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection on a temporary basis.
- Existing supplies of Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection should be reserved for clinical areas, particularly obstetrics, that cannot safely use an alternative agent, especially in emergency situations.
- NHS Trusts who have excess stock are encouraged to share stock with other local hospitals whose immediate needs may be greater.
- Following centralisation of stock, if any NHS Trust does not have enough Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection stock to support local use they should place orders for unlicensed supplies, limited amounts of which are available.

Action, to be taken by

- Hospitals in the independent sector
- Hospital pharmacies
- Hospital pharmacists
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Midwifery departments
- Midwifery staff
- Maternity units
- Theatre managers
- Theatre nurses

Deadlines for actions

Actions initiated: 05/07/2019
Actions completed: 22/07/2019

Product details

Aspen Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) Solution for Injection

Problem / background

There is a short-term supply issue affecting Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection due to delays at the manufacturing site. Aspen are the sole UK licensed supplier of Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection. Stock is currently unavailable from wholesalers and all remaining stocks are at local Trust level. Further supplies of UK licensed stock are expected by the 22nd July 2019 and we are working with Aspen to try and improve this date

Stock Management and Alternative Products

- In order to conserve existing supplies, Trusts should follow the stock management actions detailed earlier in the alert.
- Agreed management plans for areas that can use alternative options should be shared with relevant clinical colleagues and take account of whether local clinical training and support is necessary.
- Trusts with insufficient stocks locally should consider ordering unlicensed imports. NHS Trusts are reminded that orders for unlicensed product should only be considered if there is insufficient stock available of licensed Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) solution for injection.
- Aspen have identified limited stock from the Swedish and Danish market that can be imported as an unlicensed product. The product is identical to UK licensed Marcain Heavy 0.5% (bupivacaine hydrochloride anhydrous) Solution for Injection and is due to be available in the coming week. Further information about this stock including ordering details will be shared with hospital pharmacy departments in the coming days.
- Some of the specialist importer companies have identified stock from other European countries that they are importing as an unlicensed product and should be available for hospitals to order in the coming days.
- Pharmacy departments will be familiar with sourcing unlicensed products and “specials” and should be able to advise further. Before prescribing, you should liaise with your pharmacy team to clarify local availability of UK licensed product.
- When prescribing and dispensing unlicensed preparations, prescribers and pharmacists should always ensure the following:

    - Use of unlicensed products should be in line with agreed local policies and guidance.
    - Any decision to prescribe an unlicensed medicine must take into account the relevant GMC guidance and NHS Trust / Local governance procedures. Please see link to GMC guidance: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines

Enquiries

England
Send enquiries about this notice to the DH Supply Resilience Team, quoting reference number **SDA/2019/003**.

Email: supplyresiliencemd@dhsc.gov.uk

Addressees may take copies for distribution within their own organisations