Prif Swyddog Fferyllol Chief Pharmaceutical Officer





Llywodraeth Cymru Welsh Government

MEDICINES SHORTAGE ADVISORY GROUP WALES

MEDICINE SHORTAGE

	As Annex 1
Erom	
From:	Andrew Evans, Chief Pharmaceutical Officer
Date:	5 July 2019
Reference:	CPhO/MedsLet/2019/07
Category:	Level 3 - High impact
Title:	Disruption to supply of Marcain Heavy 0.5% Solution for Injection.
For Action by:	
Hospital Chief Pharmacists in the NHS and independent sector - Action as below	
 Medical Directors of Health Boards - disseminate to relevant clinicians in secondary care setting. 	
Timeframe: Action within 24 hrs	
For Information: See Annex 1 – Distribution List	
Key Recipients:	
Hospitals in the independent sector	
Hospital pharmacies	
Hospital pharmacists	
 Anaesthesia, directors of 	
Anaesthetic medical staff	
Anaesthetic nursing staff	
Anaesthetists	
 Obstetricians 	
 Obstetrics and gynaecology departments 	



Parc Cathays • Cathays Park Caerdydd • Cardiff CF10 3NQ Medicines.Shortages@gov.wales Gwefan • website: https://gov.wales/topics/health/prof essionals/pharmaceutical/?lang=en

- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Midwifery departments
- Midwifery staff
- Maternity units
- Theatre managers
- Theatre nurses

What is this about:

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.

Issue & Action to be taken:

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.

Health Boards 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 Health Board 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.

Alternative products

In order to conserve existing supplies, Health Boards 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.

Health Boards with insufficient stocks locally should consider ordering unlicensed imports. Health Boards 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 local governance procedures. Please see link to GMC guidance: <u>https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines</u>

Please forward to listed recipients.

Yours sincerely

Indrew M GS

Andrew Evans Chief Pharmaceutical Officer/Prif Swyddog Fferyllol Welsh Government/Llywodraeth Cymru

Annex 1

DISTRIBUTION LIST

Send to:

- Chief Executives of Health Boards
- Medical Directors of Health Boards
- Health Board Chief Pharmacists
- Hospital Chief Pharmacists
- Chief Executives of NHS Trusts
- Director of Welsh Medicines Information Centre
- NHS Wales Procurement

NHS Wales Shared Services Partnership to forward to:

Independent / Private clinics, hospices and hospitals throughout Wales

Welsh Government:

Chief Medical Officer Chief Nursing Officer Director General Health and Social Services Group Emergency Planning Adviser HSSG Comms