



Supply Disruption Alert

SDA/2019/011 Issued: 06 December 2019

Berinert[®] (Human C1 Esterase inhibitor) 500IU powder and solvent for injection (CSL Behring UK) – Supply Disruption Alert

Summary

- Limited stock of Berinert® 500units powder and solvent for injection (CSL Behring) remains in the supply chain.
- A detailed inventory of NHS trusts and homecare providers stock holding has identified a possible shortfall of Berinert® 500units against anticipated demand.

Action

All healthcare professionals in secondary or specialist healthcare services who prescribe, dispense or administer Berinert 500IU should:

- ensure no new long term patients are started on Berinert[®] 500IU;
- reserve all Berinert[®] 500IU stock, not held in A&E or at ward level, for use in patients who require ongoing treatment;
- review and update guidelines and protocols for the urgent treatment of Hereditary Angioedema that incorporate the use of Berinert[®], to utilise alternate agents (Cinryze[®]/ Rocunest[®]/ Firazyr[®]);
- ensure staff are adequately trained to administer the chosen alternative product;
- reassure patients who may be anxious about the prospect of interruption of treatment that the mitigations
 put in place are to prevent this;
- consider centralising remaining in-patient stock of Berinert[®] in pharmacy if any exist outside of A&E, and;
- work closely with the Commercial Medicines Unit (CMU), who are liaising with consultants and pharmacists at specialist centres, to identify cohorts of patients suitable for switching to an alternative agent over the coming 2 weeks if necessary.

Deadlines for actions

Actions initiated:	on receipt of this alert
Actions completed:	10 December 2019

Product details

Berinert[®] 500IU powder and solvent for injection

Problem / background

Berinert[®] (plasma derived Human C1 esterase inhibitor) is licensed for the treatment of acute episodes and pre-operative prevention of Hereditary angioedema type I and II (HAE). It is also used routinely off label for prevention of angioedema attacks in adults, adolescents and children.

For the last 12 months global supplies of Berinert[®] and other human plasma derived products have been constrained and it is expected this will continue in 2020.

NHS England and NHS Improvement has worked closely with CSL Behring national clinical leads and the patient advocacy group HAE UK when forming the management plan for this supply issue. Working with

specialist centers approximately 15-20 patients will be asked to switch to an alternative agent over the coming week to ensure there is sufficient stock to maintain all other patients on treatment.

The alternative products suggested are deemed to be equally effective.

A clinical guidance document has been developed by UKMi to support local management plans Link to UKMi document.

Distribution

Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists
- Hospital pharmacies
- Hospital pharmacists
- Immunologists

- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- · Intensive care, directors of
- Paediatric intensive care units
- Paediatric medicine, directors of
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers

Enquiries

England

Enquiries from NHS Trusts in England should in the first instance be directed to you trust pharmacy team who will escalate issues to the Regional Procurement Lead and national teams if required.

REGION	Full Name	Email
East Midlands	Andi Swain	andi.swain@nhs.net
East of England	James Kent	james.kent@southend.nhs.uk
London	Jackie Eastwood	jacqueline.eastwood@lpp.nhs.uk
North East	David Cook	David.Cook@nth.nhs.uk
North West	Glenn Harley	Glenn.Harley@liverpoolft.nhs.uk
South Central	Alison Ashman	Alison.Ashman@berkshire.nhs.uk
South East Coast	Richard Bateman	richard.bateman2@nhs.net
South West	Danny Palmer	Danny.Palmer@UHBristol.nhs.uk
West Midlands	Davinder Manku	davinder.manku@nhs.net
Yorkshire & Humber	David Allwood	davidallwood@nhs.net

Scotland

NSS.NHSSMedicineShortages@nhs.net Wales Tracey.Prothero@wales.nhs.uk Northern Ireland Noel.dunn@northerntrust.hscni.net

All other organisations should send enquiries about this notice to the DHSC Supply Resilience Team, quoting reference number **SDA/2019/011**

Email: supplyresiliencemd@dhsc.gov.uk