



Shortage of Erelzi® (etanercept) 50mg solution for injection in pre-filled pen

Date of issue:	3-May-24	Reference no:	NatPSA/2024/005/MVA
This alert is for action by: All organisations involved in prescribing, dispensing, and administering Erelzi® (etanercept) 50mg solution for injection in pre-filled pens			
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 rheumatology, dermatology, NHS Trust homecare lead, homecare providers and pharmacy services in all sectors.			

Explanation of identified safety issue:

Erelzi® (etanercept) 50mg solution for injection in pre-filled pen will be out of stock from early May until mid-July 2024. Homecare providers (Alcura, Healthnet and Sciensus) have sufficient stock to supply existing patients until mid/late May 2024.


The supply issues have been caused by a manufacturing failure resulting in delays in production and the implementation of global allocations.

Erelzi® 50mg pre-filled syringes (PFS) remain available, however, they cannot support a full increase in demand.

Benepali® (etanercept) 50mg solution for injection in pre-filled pens remains available and can support a full increase in demand on an ongoing basis.

Enbrel® (etanercept) 50mg solution for injection in pre-filled pens remain available and can support a full increase in demand on an ongoing basis.

The SPS [Medicines Supply Tool](#) details any changes to resupply dates, updates to this communication and an up-to-date supply overview.

Actions required 

Actions to be completed as soon as possible and not later than 10 May 2024.

Actions for clinicians, NHS Trust homecare leads and homecare providers until supply issues have resolved.

All affected providers MUST:

1. Not start any new patients on Erelzi® (etanercept) products.
2. Work with the appropriate Regional Pharmacy Procurement Specialist (RPPS) to understand individual patient needs, particularly their dexterity, to inform which patients will switch to the following alternatives (see Additional information):
 - a. Benepali® (etanercept) 50mg solution for injection in pre-filled pens;
or
 - b. Enbrel® (etanercept) 50mg solution for injection in pre-filled pens;
or
 - c. Erelzi® 50mg pre-filled syringes (PFS)
3. Secondary care pharmacy homecare teams to link in with prescribers and relevant homecare providers to clarify, implement and expedite any processes required to minimise the effects on patient care as much as possible.

Additional information:

The switch to an alternative etanercept product is complex, and partially influenced by the homecare provider with whom the Trusts contract.

1. Switching between same brand products:

All Erelzi[®] pre-filled pen homecare providers can support a switch from Erelzi[®] (etanercept) 50mg pre-filled pen to Erelzi[®] (etanercept) 50mg pre-filled syringes without any operational burden to NHS Trusts. The homecare providers will work with Sandoz to provide nurse-led training for specific patients who require any additional support.

In order to maintain the future supply chain for the Erelzi pre-filled syringes, patients switched to this product will be changed back by the homecare provider to Erelzi[®] (etanercept) 50mg pre-filled pens once the shortage is resolved.

2. Switching between different brand products:

Sciensus can support a switch from Erelzi[®] (etanercept) 50mg pre-filled pens to Benepali[®] (etanercept) 50mg pre-filled pens or Enbrel[®] 50mg pre-filled pens without any additional operational burden on the NHS.

Healthnet can support a switch from Erelzi[®] (etanercept) 50mg pre-filled pens to Benepali[®] (etanercept) 50mg pre-filled pens or Enbrel[®] 50mg pre-filled pens, however, may need additional support from the NHS Trusts with new prescriptions and completion of new patient registration forms.

Alcura can only support a switch from Erelzi[®] (etanercept) 50mg pre-filled pens to Enbrel[®] 50mg pre-filled pens and will need additional support from the NHS Trusts in regard to new prescriptions and completion of new patient registration forms.

Homecare providers and suppliers will support required patient training where patients are switched to a different brand of etanercept.

Clinical information

Erelzi is one of three licensed biosimilars to Enbrel (etanercept). It is licensed for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, plaque psoriasis, and paediatric plaque psoriasis. These products are available as a pre-filled pen or a pre-filled syringe; the latter may not be suitable for patients with arthritis or problems with manual dexterity.

References:

1. [SmPC: Erelzi[®]](#)
2. [SmPC: Benepali[®] 50mg solution for injection in pre-filled pen](#)
3. [SmPC: Enbrel[®] 50mg solution for injection in pre-filled pen](#)
4. [BNF: etanercept](#)

Stakeholder engagement:

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Service Medicine Advice, Medicine Shortage Response Group, NHS England, National Clinical Director for Musculoskeletal and national patient safety team, Medicine and Healthcare products Regulatory Agency and the Devolved Governments.

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

This is a safety critical and straightforward National Patient Safety Alert. In response to [CHT/2019/001](#) and [CHT/2023/002](#) 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 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.