SANDOZ A Novartis Division

Direct Healthcare Professional Communication

<<month and year of distribution>>

Erelzi ▼ (etanercept) 25 mg and 50 mg pre-filled syringes – limited number of batches with French syringe labels

Dear Healthcare Professional / Homecare company

This letter is sent in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA).

Summary

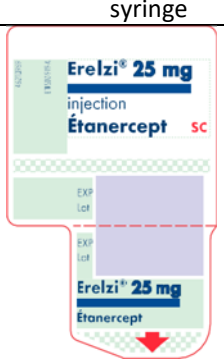
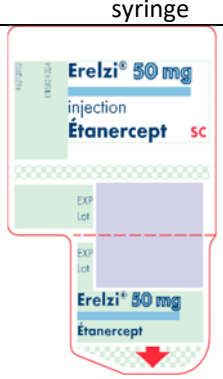
- A number of Erelzi pre-filled syringes, originally destined for France, (batch numbers and expiry dates shown below), have been repackaged for the UK.
- The products are exactly the same, the only difference between the UK and repackaged French pre-filled syringes is in the label on the syringe. See below for a comparison of the original UK and repackaged UK labels.
- If a patient or caregiver contacts you with concerns about seeing a different label for Erelzi 25 mg and 50 mg pre-filled syringes, carefully check the differences and the batch number and expiry dates below, and if they match, please reassure patients that this product is the same as their usual UK product.
- This only affects certain batch numbers of the pre-filled **syringes**. There is no impact on the 50 mg pre-filled **pens**.

Important: there is no supply issue or constraint with UK Erelzi 25 mg or 50 mg pre-filled syringes. This repackaging is for a limited time only, to re-allocate supply from France to the UK.

Table 1: Batch numbers of Erelzi 25 mg and 50 mg pre-filled syringes with French syringe labels

Product strength	Batch Number	Expiry
Erelzi 25 mg	1802140056	29-February-2020
Erelzi 50 mg	1802120022	31-January-2020
Erelzi 50 mg	1804270043	29-Febuary-2020

The original UK and repackaged UK versions of the label on the prefilled syringes are shown below:

Original UK versions		Re-packaged versions	
Erelzi 25 mg pre-filled syringe	Erelzi 50 mg pre-filled syringe	Erelzi 25 mg pre-filled syringe	Erelzi 50 mg pre-filled syringe
			

Background

The MHRA have agreed that a small number of batches of Erelzi 25 mg and 50 mg pre-filled syringes originally labelled for use in France, can be re-packaged for supply and use in the UK. The repackaging will ensure the product is identical to the original UK Erelzi pre-filled syringe packs, with the exception of the label on the syringe. The MHRA has requested that Sandoz make Homecare companies and Hospital Pharmacies who are likely to dispense the product aware of this in case a patient or carer is concerned by this small difference.

Erelzi 25 mg and 50 mg pre-filled syringes are available in boxes containing 4 pre-filled syringes. The boxes for the re-packaged batches are the same as the UK versions, it is only the individual syringes that differ. This difference is shown above (ie 'É' rather than 'e').

The difference is due to the re-packaging of product originally intended for the French market to be used in the UK. The outer carton and Patient Information Leaflet are the UK versions.

The re-packaging is part of a short-term reallocation and not due to any supply issues in either country.

Call for reporting

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. All suspected adverse reactions should be reported via the Yellow Card Scheme. It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary); by emailing yellowcard@mhra.gov.uk; at the back of the British National Formulary (BNF); by telephoning the Commission on Human Medicines

(CHM) free phone line: 0800-731-6789; or by downloading and printing a form from the Yellow Card website. When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, product brand name and batch number.

Adverse events should also be reported to Sandoz Ltd, 200 Frimley Business Park, Frimley, Surrey, GU16 7SR, email: uk.patientsafety@novartis.com or call 0845 601 1387.

Further information

Should you require additional information, please contact Medical Information via email: sandoz@professionalinformation.co.uk or by phone on: 01276 698101.

Recipients of this Direct Healthcare Professional Communication should bring it to the attention of relevant contacts by copy of this letter.

Yours sincerely,

Jo Heaton
Sandoz UK Ltd Medical Director