Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Manor Park
Runcorn
WA7 1NT
United Kingdom
www.fresenius-kabi.co.uk

21 October 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Tyenne 162 mg solution for injection in pre-filled pen (PFS) - PLGB 08828/0357: Temporary Supply of German labelled stock

Dear Healthcare Professional

Fresenius Kabi Limited in agreement with the MHRA would like to inform you of the following:

In order to prevent a supply disruption with Tyenne 162 mg pre-filled pen is providing stock with German labelling.

To ensure the continuity of supply of Tyenne 162 mg pre-filled pen Fresenius Kabi Limited has obtained approval from the MHRA to supply stock that is German labelled. The batch number concerned is shown in the table below:

Product Name	Tyenne 162 mg pre-filled pen
Presentation	Packs of 12 pre-filled syringes
Batch No	16TE0953
Expiry Date	Sep 2026

The product is expected to be on the market from August 2024 until January 2025.

Please note the following:

- The German product is the same quality, formulation and specifications as that approved in the UK.
- The only difference is the labelling is in German and the pack size is a multipack 12-pre-filled syringes (3 packs of 4). UK market is normally supplied with packs of 4 pre-filled syringes.
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.

The English product information is available for healthcare professionals to download from the electronic medicines compendium: www.medicines.org.uk

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

The German labelled product is shown below.

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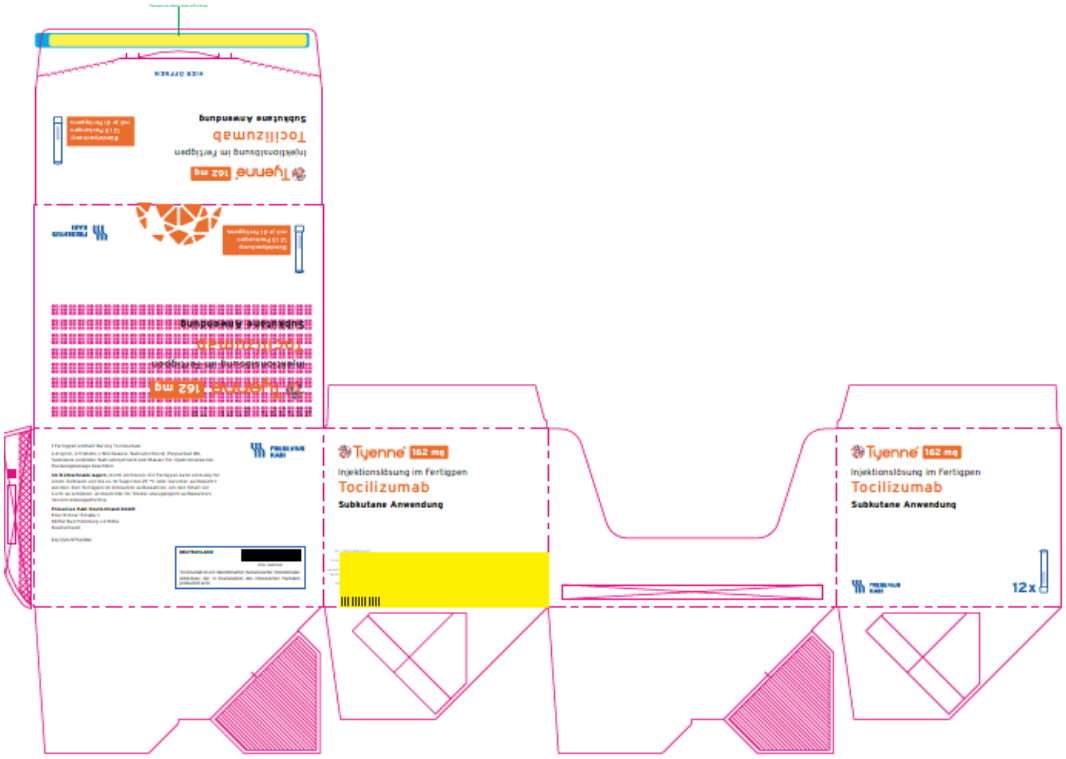
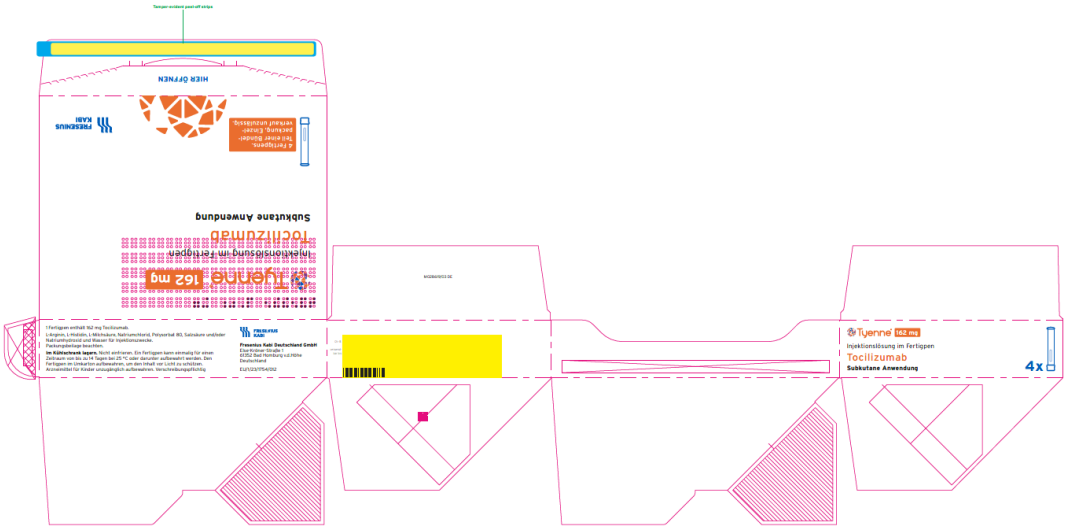
Outer Carton pack of 12 PFS



Outer Carton Packs of 4



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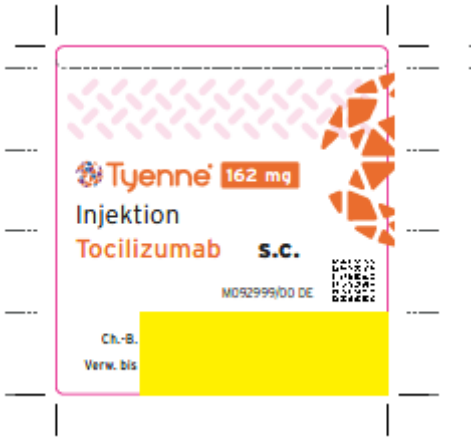
PFS Label



Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

- Tyenne▼ is subject to additional monitoring. This will allow quick identification of new safety information.

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- Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Company contact point
If you have any questions about this letter or wish more information about Tyenne 162 mg pre-filled pen**,** please contact Fresenius Kabi Limited at medical.information-UK@fresenius-kabi.com .

Yours faithfully,

Mr Carl Grealis
Regulatory Affairs Technical Lead
Fresenius Kabi Limited