Fresenius Kabi Limited
www.fresenius-kabi.co.uk

Product Storage Conditions:

Store Pre-filled syringe in a refrigerator: (2 °C – 8 °C)

Do not freeze

Protect from light

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Tyenne 162 mg solution for injection in pre-filled syringe – PLGB 08828/0358

Temporary Supply of:

Italian labelled stock

Please refer to the following pages (Pages 2 to 6)

Fresenius Kabi Limited
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12 May 2026

Dear Healthcare Professional,

Summary: Fresenius Kabi Limited is currently experiencing supply disruption with Tyenne 162 mg solution for injection in pre-filled syringe in the United Kingdom

To ensure continuity in supply, Fresenius Kabi Limited has obtained approval from the MHRA to supply Italian product (batch number: 16UL5405, batch size: 8,640 units), which is expected to be on the UK market from May till the expiry date. Healthcare professionals should note that the storage conditions are not clear on the packs which need to be stored in a refrigerator (2 °C – 8 °C).

Concerned batch details are given in the table below:

Product Name	Tyenne 162 mg pre-filled syringe (Italian labelled)
Presentation	Packs of 4 pre-filled syringes,
Batch No	16UL5405
Expiry Date	31 October 2028
Storage Conditions	Store Pre-filled syringes in a refrigerator (2 °C –8°C). Do not freeze. Protect from light.

Please note the following:

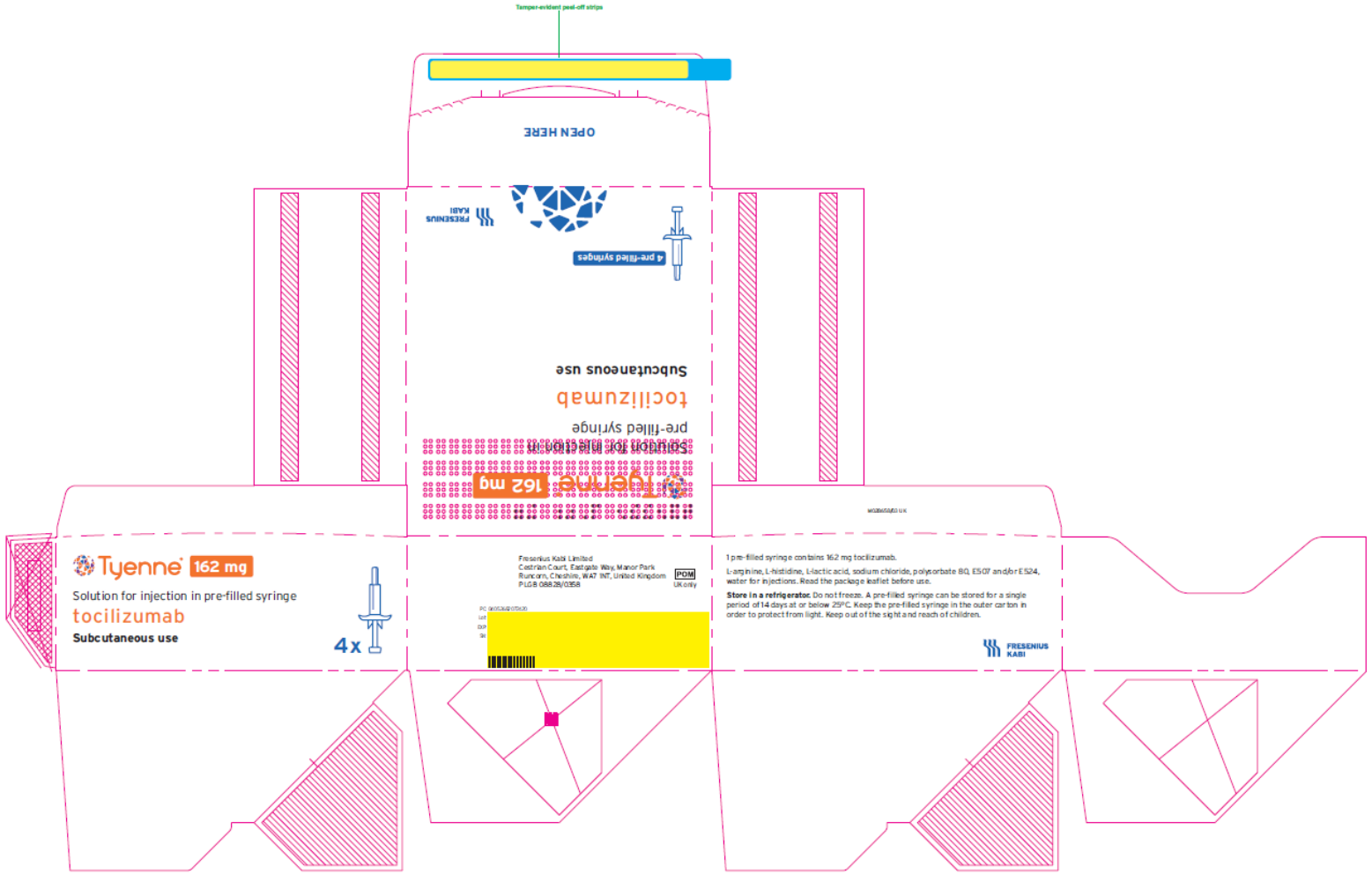
- **Store Pre-filled syringe in a refrigerator (2 °C – 8 °C). Do not freeze. Protect from light.**
- The Italian product is the same quality, formulation and specifications as that approved in the UK.
- The only difference is the labelling is in Italian. The pack size is the same as approved in the UK.
- 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

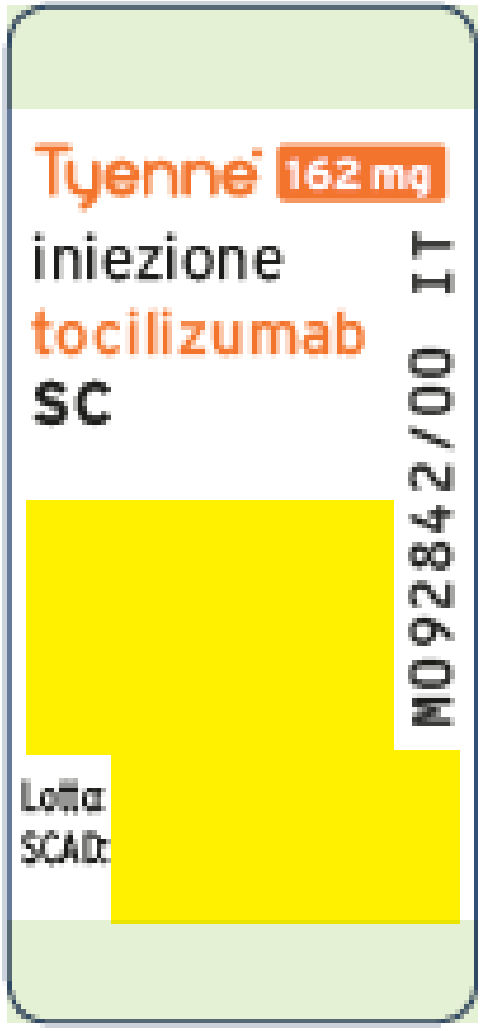
Please ensure all relevant staff are made aware of the storage instructions for the product detailed in this letter and that the information is communicated to the patients.

The Italian labelled product is shown below.

Outer Carton Packs of 4 PFS(Item code M028359/01 IT)



PFS Inner Label(Item code: M092842/00 IT)



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.

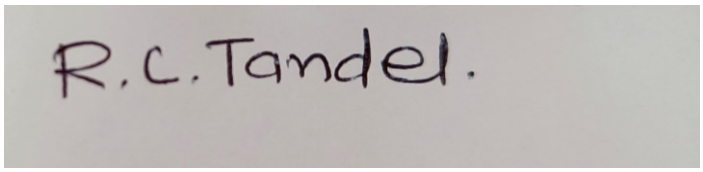
Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

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 syringe**,** please contact Fresenius Kabi Limited at medical.information-UK@fresenius-kabi.com .

Yours faithfully,



Riddhi Tandel
Regulatory Affairs Officer
Fresenius-Kabi Ltd