

Best-Value Medicine (Tocilizumab): Tyenne®

Information for Healthcare Professionals

The MMP recommends Tyenne® as a Best Value Biological (BVB) Medicine for tocilizumab on the High Tech Arrangement.

Prescribing Tyenne® reduces the financial burden on the HSE arising out of the funding of reimbursed medicines, and can assist in facilitating access to new, innovative medicines for patients.

The following presentations of Tyenne®^{▼1,2} are recommended as best-value biological (BVB) medicines:

- Tyenne® 162 milligrams (mg) solution for injection in pre-filled pen
- Tyenne® 162 mg solution for injection in pre-filled syringe

The pre-filled pen (PFP) and pre-filled syringe (PFS) presentations of Tyenne® are on the HSE Reimbursement List, for prescribing and supply on the High Tech Arrangement.

Tyenne® is a biosimilar medicine. This means that Tyenne® is highly similar to another biological medicine (the reference medicine) that is already authorised in the European Union. The reference medicine for Tyenne® is RoActemra®.

This product information sheet provides information to support clinical teams when prescribing the PFP and PFS presentations of Tyenne® for patients. The Summary of Product Characteristics (SmPC) for Tyenne® should be referred to for full prescribing information.

Tyenne® 162 mg pre-filled pen



- Each pack contains four single-use PFPs
- Each PFP contains 162 mg of tocilizumab in 0.9 millilitres (mL).
- There is no latex present in the PFP; Tyenne® is therefore suitable for patients with a latex allergy.
- It is supplied as a clear and colourless to pale yellow solution for injection.
- The PFP is equipped with a 27-gauge needle, with a length of 12.7 millimetres (mm).

¹▼ This medicinal product is subject to additional monitoring

²Please refer to the Summary of Product Characteristics of Tyenne® for full prescribing information.

Storage

- Tyenne® PFP should be stored in a refrigerator (2°C – 8°C). It should not be frozen.
- The PFP should be kept in the outer carton of the packaging in order to protect it from light.
- A single Tyenne® PFP may be stored at room temperature (up to 30°C) for a single period of up to 14 days. The PFP must be protected from light, and discarded if not used within the 14-day period at room temperature (up to 30°C) or by the original expiry date, whichever is earlier.

Dose Administration

- The patient information leaflet contains instructions in both text and diagrammatic form, on how to administer a dose from the Tyenne® PFP. This should be used as the primary source of information in relation to administration of Tyenne® PFP.
- Tyenne® PFP should not be used if the solution is cloudy or contains particles, is any colour besides colourless to pale yellow, or any part of the PFP appears to be damaged. The PFP should not be shaken.
- Prior to administration, Tyenne® PFP should be allowed to reach room temperature after removing from the refrigerator, by waiting for 45 minutes before injecting. Once stored at room temperature, do not place back in the refrigerator.
- After removing the cap, the injection must be started right away, to prevent the medicine from drying out and blocking the needle. If the injection is not used right away after removing the cap, it should be disposed of in an appropriate manner and a new PFP should be used.
- Delivery of the dosage commences when the patient pushes the PFP firmly against their skin, at a 90-degree angle, until they hear a first click.
- The orange plunger rod will move through the window during the injection (this means the injection has started).
- The patient should continue to hold the PFP in place until they hear a second click. This may take up to 10 seconds.
- The patient should wait and slowly count to five after they heard the second click. The patient should continue to hold the PFP in place to ensure the full dosage is injected.
- While holding the PFP in place, the window should be checked to ensure the orange plunger rod has fully appeared in the viewing window, and has stopped moving.
- When the injection is complete, the PFP should be lifted straight away from the skin. The needle cover will slide down and cover the needle.

Similarities between Tyenne® and the reference biological medicine (RoActemra® pre-filled pen)

- Both Tyenne® PFP and RoActemra® PFP have a shelf life of three years.
- Both Tyenne® PFP and RoActemra® PFP are single-use PFPs.
- Both Tyenne® PFP and RoActemra® PFP should not be shaken.
- A Tyenne® PFP may be stored at room temperature (up to 30°C) for a single period of up to 14 days. The PFP must be protected from light, and discarded if not used within the 14-day period at room temperature (up to 30°C) or by the original expiry date, whichever is earlier. Once removed from the refrigerator, a RoActemra® PFP can be stored for up to two weeks at or below a temperature of 30°C.
- Prior to administration, both Tyenne® PFP and RoActemra® PFP should be allowed to reach room temperature after removing from the refrigerator, by waiting for 45 minutes before injecting.
- Both Tyenne® PFP (orange) and RoActemra® have a coloured indicator window to signify when administration of the dosage of tocilizumab is complete.
- Both Tyenne® PFP and RoActemra® PFP have a safety feature to guard the needle upon delivery of the dose of tocilizumab; once the PFP is lifted away from the skin, a needle shield covers the needle.

Differences between Tyenne® and the reference biological medicine (RoActemra® pre-filled pen)

- Delivery of the dose from the Tyenne® PFP commences when the patient pushes the PFP firmly against their skin and they hear an initial click. For RoActemra® PFP, the patient is required to press the green activation button to commence delivery of the dose of tocilizumab.
- Once the cap is removed from Tyenne® PFP, the injection must be started right away, to prevent the medicine from drying out and blocking the needle. If the injection is not used right away, the PFP should be disposed of in an appropriate manner and a new PFP should be used. Once the cap is removed from RoActemra® PFP, the injection must be started within three minutes, to prevent the medicine from drying out and blocking the needle. If the injection is not used within three minutes of removing the cap, the PFP must be disposed of in an appropriate manner and a new PFP should be used.



Tyenne® 162 mg pre-filled syringe



- Each pack contains four single-use PFS.
- Each PFS contains 162 mg of tocilizumab in 0.9 mL.
- There is no latex present in the PFS; Tyenne® is therefore suitable for patients with a latex allergy.
- It is supplied as a clear and colourless to pale yellow solution for injection.
- The PFS is equipped with a 27-gauge needle, with a length of 12.7 mm.

Storage

- Tyenne® PFS should be stored in a refrigerator (2°C – 8°C). It should not be frozen.
- The PFS should be kept in the outer carton of the packaging in order to protect it from light.
- A single Tyenne® PFS may be stored at room temperature (up to 30°C) for a single period of up to 14 days. The PFS must be protected from light, and discarded if not used within the 14-day period at room temperature (up to 30°C) or by the original expiry date, whichever is earlier.

Dose Administration

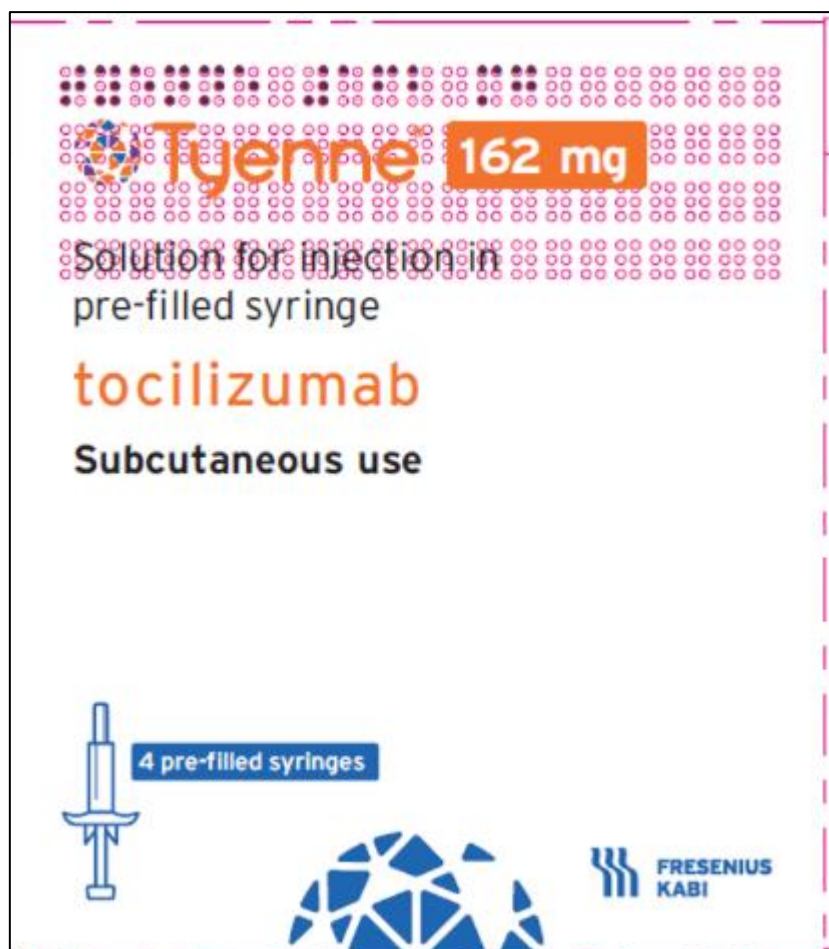
- The patient information leaflet contains instructions in both text and diagrammatic form, on how to administer a dose from the Tyenne® PFS. This should be used as the primary source of information in relation to administration of Tyenne® PFS.
- Tyenne® PFS should not be used if the solution is cloudy or contains particles, is any colour besides colourless to pale yellow, or any part of the PFS appears to be damaged. The PFS should not be shaken.
- Prior to administration, Tyenne® PFS should be allowed to reach room temperature after removing from the refrigerator, by waiting for at least 30 minutes before injecting. Once stored at room temperature, do not place back in the refrigerator.
- After removing the cap, the injection must be started right away, to prevent the medicine from drying out and blocking the needle. If the injection is not used right away after removing the cap, it should be disposed of in an appropriate manner and a new PFS should be used.
- Delivery of a dose commences when the patient, using their thumb, gently pushes the orange plunger all the way down.
- To deliver the full dose, the patient should keep pressing down on the plunger until you cannot press anymore.
- The thumb should then be slowly released off the plunger; the plunger will move up.
- The safety system will remove the needle from the skin and cover the needle.

Similarities between Tyenne® and the reference biological medicine (RoActemra® pre-filled syringe)

- Both Tyenne® PFS and RoActemra® PFS have a shelf life of three years.
- Both Tyenne® PFS and RoActemra® PFS are single use PFS.
- Both Tyenne® PFS and RoActemra® PFS should not be shaken.
- Tyenne® PFS may be stored at room temperature (up to 30°C) for a single period of up to 14 days. The PFS must be protected from light, and discarded if not used within the 14-day period at room temperature (up to 30°C) or by the original expiry date, whichever is earlier. Once removed from the refrigerator, RoActemra® PFS can be stored for up to two weeks at or below a temperature of 30°C.
- Both PFS presentations have a safety feature to guard the needle upon delivery of the dose of tocilizumab, with a passive needle guard system in place, i.e. upon release of the plunger having administered the dose, the entire needle is drawn back automatically and covered by the needle safety guard.

Differences between Tyenne® and the reference biological medicine (RoActemra® pre-filled syringe)

- After removing the Tyenne® PFS from the refrigerator, the PFS should be allowed to reach room temperature by waiting for at least 30 minutes, before injecting. After removing the RoActemra® PFS from the refrigerator, the PFS should be allowed to reach room temperature (18°C to 28°C) by waiting for 25 to 30 minutes, before injecting.
- Once the cap is removed from Tyenne® PFS, the injection must be started right away, to prevent the medicine from drying out and blocking the needle. If the injection is not used right away, the PFS should be disposed of in an appropriate manner and a new PFS should be used. Once the cap is removed from RoActemra® PFS, the injection must be started within five minutes, to prevent the medicine from drying out and blocking the needle. If the injection is not used within five minutes of removing the cap, the PFS must be disposed of in an appropriate manner and a new PFS should be used.



Fresenius Kabi Ireland Patient Support Services

Fresenius Kabi Ireland provide a patient support programme to patients who have been prescribed Tyenne® 162 mg solution for injection PFP/PFS. This is provided by Hibernian Healthcare at Home on behalf of Fresenius Kabi Ireland.

The following services are available at no charge to patients prescribed Tyenne® following a referral by their prescriber:

- Provision of up to two nurse home visits to deliver patient education and training on correct injection and administration technique for Tyenne® PFS/PFP. This can be delivered remotely, if required.
- Sharps management service – this includes supply, collection and disposal of a sharps bin
- Post-home visit report shared with the referring healthcare professional
- Access to a helpline for patient queries and compliance adherence phone call
- Provision of QuantiFERON testing
- Provision of patient support materials, e.g. patient starter pack for Tyenne® PFP/PFS, access to an online education resource, i.e. Kabicare.

In order to avail of the patient support services for patients who have been prescribed Tyenne®, please use the Hibernian Healthcare at Home online portal

<https://schedule.hahirl.com/>

If you have not registered on the Hibernian Healthcare at Home online portal previously, please contact Hibernian Healthcare at Home at 01 460 4792 or by email at

info@hibernianhealth.com, and access and support will be provided.

In order to obtain training pens and patient support materials for use in clinics, please contact:

- Email: stuart.mackenzie-smith@fresenius-kabi.com
- Phone: (087) 353 2622

References:

1. Fresenius Kabi Deutschland GmbH. Tyenne® 20 mg/mL concentrate for solution for infusion, Tyenne® 162 mg solution for injection in pre-filled syringe, Tyenne® 162 mg solution for injection in pre-filled pen. Summary of Product Characteristics. Last updated 02/10/2025. Accessed at www.ema.europa.eu on 18/12/2025.
2. Roche Registration GmbH. RoActemra® 20 mg/mL concentrate for solution for infusion, RoActemra® 162 mg solution for injection in pre-filled syringe, RoActemra® 162 mg solution for injection in pre-filled pen. Summary of Product Characteristics. Last updated 06/05/2025. Accessed at www.ema.europa.eu on 18/12/2025.