

Best-Value Medicine (Tocilizumab): Avtozma®

Information for Healthcare Professionals

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

Prescribing Avtozma® 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 Avtozma®^{1,2} are recommended as best-value biological (BVB) medicines:

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

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

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

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

Avtozma® 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; Avtozma® is therefore suitable for patients with a latex allergy.
- It is supplied as a clear to slightly opalescent, colourless to yellow solution for injection.
- The PFP is equipped with a 26-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 Avtozma® for full prescribing information.

Storage

- Avtozma[®] 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 and moisture.
- Once removed from the refrigerator, a single Avtozma[®] PFP can be stored for up to three weeks at or below a temperature of 30°C. The PFP must be discarded if not used within the three-week period. If necessary, the PFP may be returned to the refrigerator once within these three weeks and stored in a refrigerator (between 2°C – 8°C) until the expiry date.

Dose Administration

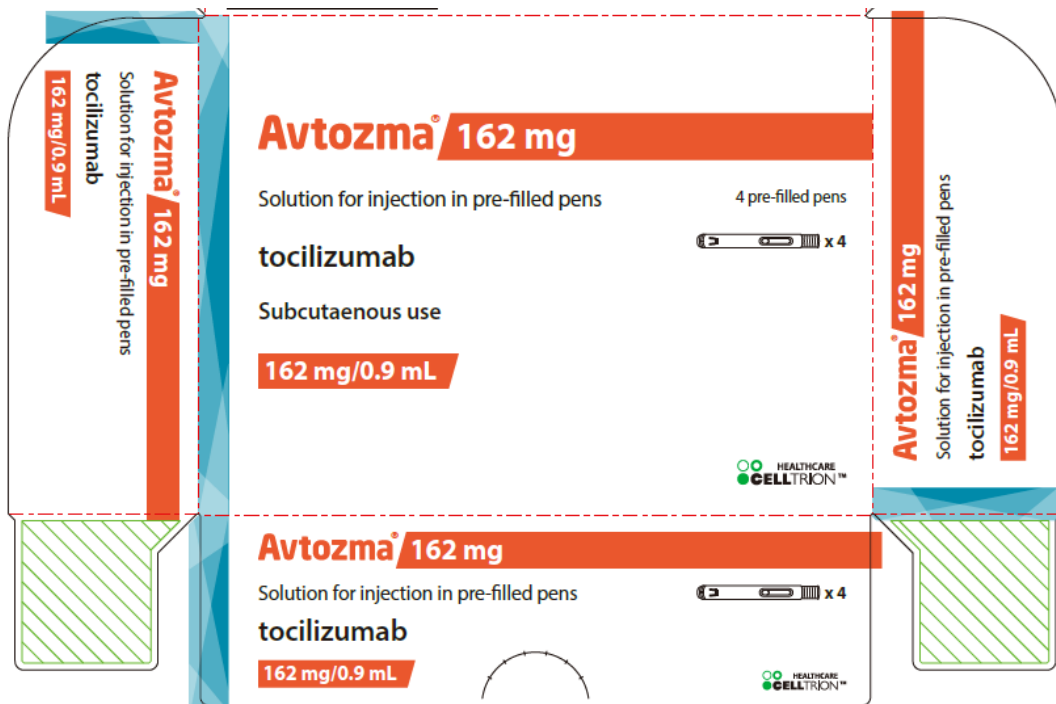
- The patient information leaflet contains instructions in both text and diagrammatic form, on how to administer a dose from the Avtozma[®] PFP. This should be used as the primary source of information in relation to administration of Avtozma[®] PFP.
- Avtozma[®] PFP should not be used if the solution is cloudy or contains particles, is any colour besides colourless to yellow, or any part of the PFP appears to be damaged. The PFP should not be shaken.
- Prior to administration, Avtozma[®] PFP should be allowed to reach room temperature (18°C to 28°C) after removing from the refrigerator, by waiting for 45 minutes before injecting.
- After removing the cap, 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, it should be disposed of in an appropriate manner and a new PFP should be used.
- Delivery of the dosage commences when the patient presses the PFP firmly into their skin, at a 90-degree angle, until they hear a first click and the orange indicator will begin to fill the window area.
- The patient should continue to hold the PFP in place until they hear a second click.
- 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.
- The patient should watch the orange indicator until it stops moving and has reached the end of the window to ensure the full dose of medicine is injected.
- When the orange indicator has stopped moving, the PFP should be lifted straight off of the injection site at a 90-degree angle. The needle cover will automatically move out and lock into place covering the needle.

Similarities between Avtozma[®] and the reference biological medicine (RoActemra[®] pre-filled pen)

- Both Avtozma[®] PFP and RoActemra[®] PFP are single-use PFPs.
- Both Avtozma[®] PFP and RoActemra[®] PFP should not be shaken.
- Prior to administration, both Avtozma[®] PFP and RoActemra[®] PFP should be allowed to reach room temperature after removing from the refrigerator, by waiting for 45 minutes before injecting.
- Once the cap is removed from both Avtozma[®] PFP and 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.
- Both Avtozma[®] PFP (orange) and RoActemra[®] have a coloured indicator window to signify when administration of the dosage of tocilizumab is complete.
- Both Avtozma[®] 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 Avtozma® and the reference biological medicine (RoActemra® pre-filled pen)

- Avtozma® PFP has a shelf life of four years. RoActemra® PFP has a shelf life of three years.
- Once removed from the refrigerator, Avtozma® PFP can be stored for up to three weeks at or below a temperature of 30°C. The Avtozma® PFP must be discarded if not used within the three-week period. If necessary, the Avtozma® PFP may be returned to the refrigerator once within these three weeks and stored refrigerated until the expiry date. Once removed from the refrigerator, a RoActemra® PFP can be stored for up to two weeks at or below a temperature of 30°C.
- Delivery of the dose from the Avtozma® PFP commences when the patient presses the PFP firmly into 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.



Avtozma® 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; Avtozma® is therefore suitable for patients with a latex allergy.
- It is supplied as a clear to slightly opalescent, colourless to yellow solution for injection.
- The PFS is equipped with a 26-gauge needle, with a length of 12.7 mm.

Storage

- Avtozma® 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 and moisture.
- Once removed from the refrigerator, a single Avtozma® PFS can be stored for up to three weeks at or below a temperature of 30°C. The PFS must be discarded if not used within the three-week period. If necessary, the PFS may be returned to the refrigerator once within these three weeks and stored refrigerated until the expiry date.

Dose Administration

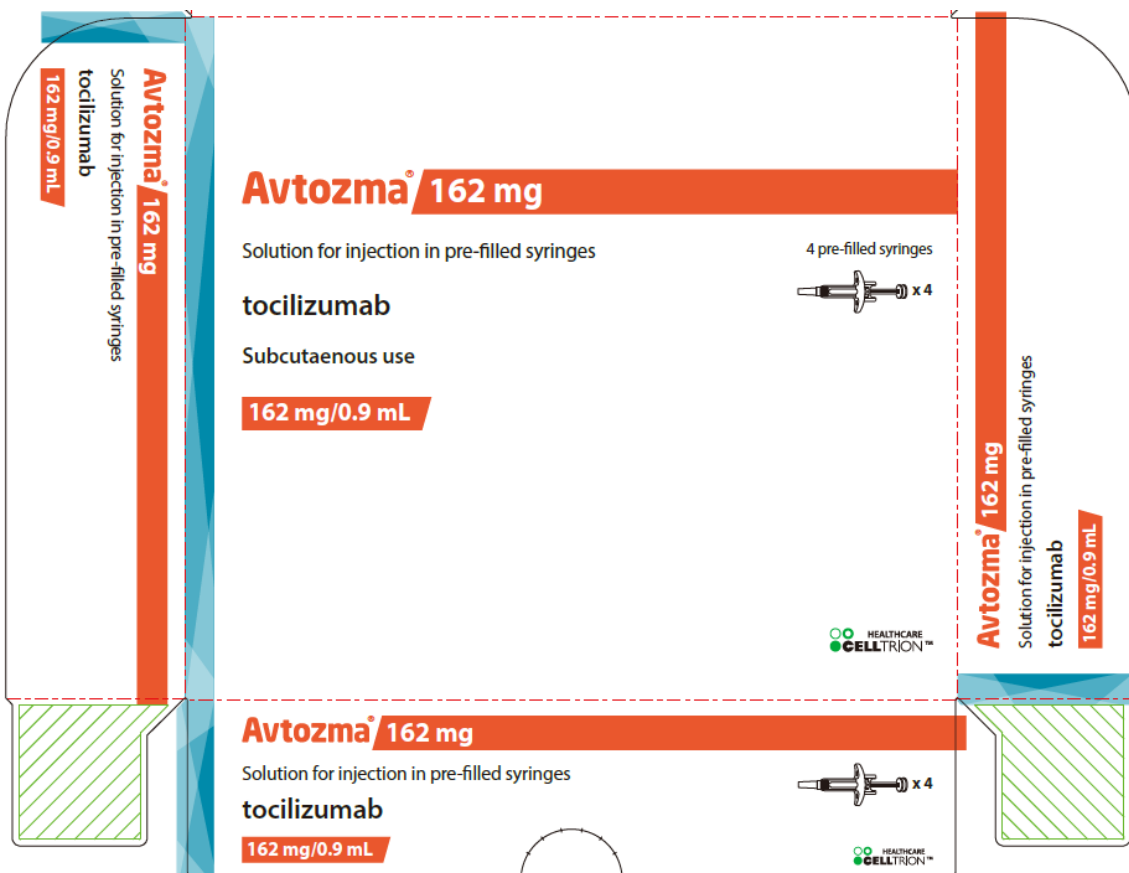
- The patient information leaflet contains instructions in both text and diagrammatic form, on how to administer a dose from the Avtozma® PFS. This should be used as the primary source of information in relation to administration of Avtozma® PFS.
- Avtozma® PFS should not be used if the solution is cloudy or contains particles, is any colour besides colourless to yellow, or any part of the PFS appears to be damaged. The PFS should not be shaken.
- Prior to administration, Avtozma® PFS should be allowed to reach room temperature (18°C to 28°C) after removing from the refrigerator, by waiting for 30 minutes before injecting.
- After removing the cap, 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, 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 until the full dose is injected and the syringe is empty.
- Once the dose is delivered, remove the needle from the injection site and release the plunger.
- The needle will then be covered by the guard.

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

- Both Avtozma® PFS and RoActemra® PFS are single use PFS.
- Both Avtozma® PFS and RoActemra® PFS should not be shaken.
- Once the cap is removed from both Avtozma® PFS and 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.
- 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 Avtozma® and the reference biological medicine (RoActemra® pre-filled syringe)

- Avtozma® PFS has a shelf life of four years. RoActemra® PFS has a shelf life of three years.
- Once removed from the refrigerator, Avtozma® PFS can be stored for up to three weeks at or below 30°C. The Avtozma® PFS must be discarded if not used within the three-week period. If necessary, the Avtozma® PFS may be returned to the refrigerator once within these three weeks and stored refrigerated until the expiry date. Once removed from the refrigerator, a RoActemra® PFS can be stored for up to two weeks at or below a temperature of 30°C.
- After removing the Avtozma® PFS from the refrigerator, the PFS should be allowed to reach room temperature (18°C to 28°C) by waiting for 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.



Celltrion Healthcare Ireland Patient Support Services

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

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

- Provision of a nurse home visit to deliver patient education and training on correct injection and administration technique for Avtozma[®] PFP/PFS. This can be delivered remotely, if required. Additional nurse home visits can be provided, if required. This service includes the provision of training for administration of Avtozma[®] PFP/PFS to paediatric patients
- 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 text, email, or call reminders to aid adherence
- Provision of QuantiFERON testing
- Provision of patient support materials, e.g. patient starter pack for Avtozma[®] PFP/PFS
- Provision of cool bag and travel kit to support travel.

In order to avail of the patient support services for patients who have been prescribed Avtozma[®], 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: Enquiry_IE@celltrionhc.com
- Phone: 01 223 4026

References:

1. Celltrion Healthcare Hungary Kft. Avtozma[®] 20 mg/mL concentrate for solution for infusion, Avtozma[®] 162 mg solution for injection in pre-filled syringe, Avtozma[®] 162 mg solution for injection in pre-filled pen. Summary of Product Characteristics. Last updated 26/01/2026. Accessed at www.ema.europa.eu on 28/04/2026.
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 01/04/2026. Accessed at www.ema.europa.eu on 28/04/2026.