

Actemra and Storage Temperature Excursion

This letter responds to your request for information on Actemra® (tocilizumab) and storage temperature excursion.

Prescribing Information

- Actemra vials, prefilled syringes (PFS), and autoinjectors must be refrigerated at 2°C to 8°C (36°F to 46°F). The product should not be frozen. Additionally, the vials, syringes, and autoinjectors should be protected from light by storage in the original package until time of use; the syringes and autoinjectors should also be kept dry.
- Prior to use, the PFS should be removed from the refrigerator and allowed to sit at room temperature outside of the carton for 30 minutes.
- Prior to use, the autoinjector should be removed from the refrigerator and allowed to sit at room temperature outside of the carton for 45 minutes.

Storage Temperature Excursion Information

- The following information applies to healthcare facilities or pharmacies preparing Actemra for administration or dispensing Actemra to patients. It does not apply to temperature excursions that may occur during shipping and/or transportation before arrival at the healthcare facility or pharmacy.
- The following information applies to product where the vial stopper has not been punctured (vial), or needle cap (PFS) or green cap (autoinjector) removed.
- From the time the Actemra vial arrives at the healthcare facility or pharmacy until the vial stopper is punctured, a maximum cumulative time of up to 24 hours duration is permitted for the vial to be at temperatures above 8°C (46°F) to ≤30°C (86°F).¹
- After the Actemra PFS or autoinjector has been dispensed to the patient, a maximum cumulative time of up to 8 hours is permitted for the PFS or autoinjector to be at temperatures above 8°C (46°F) to ≤30°C (86°F).²
- Storage temperature excursion between 0°C (32°F) to <2°C (<36°F) is not anticipated to pose a risk to product stability.¹
- Do not use product if it has been exposed to temperatures below 0°C (32°F) or above 30°C (86°F).¹
- In the event that a storage temperature excursion is identified and the excursion is within the stated parameters, the product should be returned immediately to the recommended storage condition of 2°C to 8°C (36°F to 46°F) and used as soon as it is feasible.

Actemra and Storage Temperature Excursion References

1. Data on file (np41ssimv114v8871g2mieilqs).
2. Data on file (blbkgu65a49kfaa3d60iubo5f0).