

Actemra SC Patient Convenience Time Storage Conditions

This letter responds to your request for information on the patient convenience time storage conditions of the subcutaneous formulation of Actemra® (tocilizumab).

Please refer to the stability information provided in the manufacturers label. Any deviation from this information is considered off-label and any treatment decisions based on such deviations are the full responsibility of the prescribing physician.

Recommendation for Actemra SC storage at temperatures outside of 2°C to 8°C

Once removed from the refrigerator, the pre-filled syringe (PFS) or autoinjector pre-filled pen can be stored up to 2 weeks at or below 30°C.¹

This 2-week period is referred to as the patient convenience time. The purpose of the patient convenience time is to allow more time at or below 30°C to be used at the patient's discretion.¹

Recommendation for Actemra SC storage conditions

The PFS or pre-filled pen must be kept in the carton in order to be protected from light and mechanical stress.

Using the 2-week patient convenience time

The 2-week patient convenience time is solely reserved for the discretion of the patient, including any steps needed for handling of Actemra by the patient. The 2-week period starts once the product is in the patient's possession. This could include

- transportation time from the pharmacy to the patient's home,
- administration time, or
- transportation time when the patient is traveling.¹

The 2-week patient convenience time applies for each individual syringe. It starts when Actemra SC is removed from cold storage at 2°C to 8°C and ends either when placed back into cold storage or when administered.

Tracking the 2-week patient convenience time

The patient convenience time is cumulative, which means each syringe may be exposed to several excursions (e.g., may be removed from the refrigerator and put back prior to use) as long as the total cumulative time does not exceed a maximum of 2 weeks, and the temperature exposure does not exceed 30°C. It is therefore critical to ensure that all individual excursion durations are tracked.

Excursion tracking example

A patient receives Actemra SC at the pharmacy and travels 1 hour back to their home. They then go on a trip, that includes a 5-hour flight. The total excursion time during that trip from refrigerator-to-refrigerator is 7 hours.

Out of the 336 hours (14 days x 24 hours) of total patient convenience time allowed, the patient has used up 8 hours. There are 328 hours remaining of patient convenience time for that Actemra SC product.

Reference

1. Roche Internal Technical Report (Accessed on 27 January 2023).