

Colmenar Viejo, 13 May 2019

To whom it may concern

Stability of Yondelis® outside the storage and distribution requirements (2°C – 8°C)

According to the stability studies performed at accelerated condition ($25^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and $60\% \text{ RH} \pm 5\% \text{ RH}$) and freezer condition ($-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$).

I hereby inform that:

The maximum time that Yondelis® may be kept at room temperature or below $+ 2^{\circ}\text{C}$ is no more than five (5) days (120 hours).

This information only has to be used to deal with unexpected and unplanned excursion from the storage conditions ($2^{\circ}\text{C} - 8^{\circ}\text{C}$) and not for justifying planned deviations.

If a temperature excursion occurs outside the required storage and distribution conditions but within the mentioned time, the medication could be stored again at the fridge and could be used. If the time is exceeded, please contact with Pharma Mar's representatives.


Olimpia Peláez
Qualified Person