KETALAR - Stability after Opening and Dilution

This letter regarding ketamine hydrochloride may include information of an off-label nature. Pfizer does not suggest or recommend the use of ketamine hydrochloride in any manner other than as described in the Prescribing Information. Refer to the regulatory approved Local Prescribing Information for full prescribing information. Where the product is not marketed in your country location, all information in this document is off-label.

STORAGE GUIDELINES

Pfizer cannot guarantee the stability or recommend the use of any product that was stored outside of the storage conditions on the Product Label or Patient Information Leaflet. Use of a product outside of the labeled conditions constitutes off-label use and is done at the discretion of the institution or HCP.

Further information provided is for individual customer use and is not intended to be used for shipping purposes or for future excursions.

Note that if data is available, it is based on physical stability testing only; product stored outside the recommended temperature range would not be tested or evaluated for safety or efficacy.

LITERATURE SEARCH

We are aware that there may be published data (e.g., in Trissel, Micromedex or published articles) that have investigated the stability of ketamine hydrochloride when stored in conditions that are inconsistent with the recommendations in the Prescribing Information. Please note, however, that we do not provide this published data because the product(s) and formulation(s) discussed in the published data may not represent the Ketalar formulation, as marketed by Pfizer. Furthermore, we are unable to assess the validity of the test methods and their applicability to Ketalar. Therefore, the conclusions in the published data may not apply to Ketalar.

INTERNAL DATA

After Opening:

The Ketalar product was not formulated as multiple dosing presentations. The opened vial is for single use only and should be used immediately. Unused product should be discarded. The formulation of Ketalar contains an ingredient which can function as an antimicrobial preservative, benzethonium chloride, but the product is not designed or tested as a multi-use product.[1]

After Dilution

The chemical and physical stability has been demonstrated for 48 hours at 25 °C for drug product diluted with Dextrose 5% (glucose 50 mg/mL) or normal Saline (sodium chloride 9 mg/mL).[2]

From a microbiological point of view, the reconstituted and diluted solutions should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 12 hours at 2-8°C, unless reconstitution and dilution have taken place in controlled and validated aseptic conditions.

REFERENCES

1 Ketamine hydrochloride Data on file (E15). Pfizer.
2 Ketamine hydrochloride Data on file (E59). Pfizer.