

Fresenius Kabi Deutschland GmbH, 61169 Friedberg

To whom it may concern

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September 20, 2022

Coloration of Pemetrexed 25 mg/ml, concentrate for solution for infusion

Statement

To all who may be interested, Fresenius Kabi Deutschland GmbH, PU Third Party Manufacturing, hereby confirm that the above mentioned medicinal product is highly light sensitive. The approved coloration of solution ranges from slightly yellowish to yellow-greenish solution throughout the shelf-life of the product. The coloration of product solution is assessed in line with Ph.Eur. 2.2.2

Discoloration of the product originates from the exposure to light and/or heat which has to be avoided. The product needs to be kept in the individual protective carton box until directly used.


The stability data of Pemetrexed Fresenius Kabi 25mg/ml, concentrate for solution for infusion, clearly demonstrate the stability of the drug product over a period of 24 months. Due to the documented result the applicant therefore claims a shelf-life of 24 months taking into consideration of the storage condition "Keep the vial in the outer carton in order to protect from light".

Additionally, a presentation of the product behaviour is attached to this statement.

Kind regards,

Fresenius Kabi Deutschland GmbH

Dr. Lars Tausch
Qualified Person

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