



Issue Date: 25th January 2020

SAFETY ALERT NOTICE.

Drug / Product / Device : **Cyklokapron – Tranexamic Acid**

Identified Issue / Concern / Problem/ Evidence of harm.

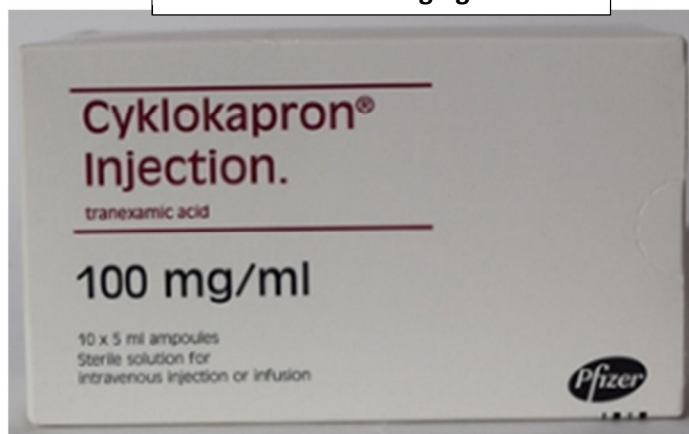
Pfizer – the manufacturer has advised that the product labelling of Cykloapron solution has changed from **Cykloapron 500mg/5ml to Cykloapron 100mg/ml**

Actions Required / Risk Treatment strategy

There is no change in the concentration or posology of the medicinal product but there is a risk of confusion when faced with a different labelling format or products of differing label formats as the batches transition through our supply chain. The Health Products Regulatory Authority has requested the issue of a caution in use notice to those who may prescribe, dispense or administer this product.

No special action is required other than to be aware of the change in labelling and be familiar with this change.

New Packaging:



Issued by: Quality, Safety & Risk – North Leinster.