NHS England

Product specification: Fluorouracil in Elastomeric Infusion Devices

	Name of product	Fluorouracil in elastomeric infusion device. Aseptically prepared from licensed sterile starting materials.
	Doses	Dose range in accordance with the national dose banding tables in sterile elastomeric infusion devices & variable fill volumes.
	Diluent	Sodium Chloride Injection 0.9% w/v
	Volume	Various fill volumes depending on the infusion rate of the device
	Final container	CE marked sterile elastomeric infusion devices **Example devices:** Accufuser (Q Medical Technologies) Autofuser (Teleflex) Dosifuser (Spirit Medical) Folfuser LV/SV (Baxter) Surefuser (Nipro Medical) Easy Pump 2 (B Braun) **Example Flow rates used:** 0.5ml/hr to 5ml/hr
	Starting materials	Licensed Fluorouracil 25 or 50mg/ml solution for Injection to allow centres to continue using their preferred strength Licensed Sodium Chloride Injection 0.9% w/v CE marked elastomeric infusion device
	Labelling	Labelling must be compliant with the principles of labelling for safety and the BP General specification on unlicensed medicines. There is no requirement for Tall Man lettering for the drug name.
	Label sample	An example label is provided below stating the minimum requirements only (the label format is not restrictive and suppliers can use their preferred layout):- .
	Batch Number	All products will have a unique batch identification number
	Latex status of - components - manufacturing process	All materials and manufacturing processes will be latex free or clearly labelled if not.
	Stability	Stability studies should conform to the Standard Protocol for deriving and assessment of stability of Aseptic preparations (small molecules) published by the NHS Pharmaceutical QA Committee (4th Edition, April 2017).

Fluorouracil xxxxmg
in xxxml Sodium Chloride 0.9% w/v
Infused at xxx ml/hour
For Intravenous Infusion
Infuse the entire contents of the device
Check the solution is free from particles before administering

Store at Room Temperature — Protect From Light
Expiry: dd/mm/yyyy — BN: XXXXXXXXX
Keep out of the reach and sight of children
Manufacturer's details — MS XXXXXX
Caution Cytotoxic: Handle with care