NHS England

Product specification: Thiotepa 250ml & 500ml & 1000ml infusion

	Name of product	Thiotepa infusion. Aseptically prepared from licensed sterile starting materials.
	Concentration	Concentration range 0.5mg/ml to 1mg/ml in infusion bags in accordance with the national dose banding tables. The Thiotepa concentrate should be added to the bag without withdrawal of equivalent volume of Sodium Chloride 0.9% w/v Infusion unless withdrawal of some infusion fluid is required to accomodate the total dose.
	Diluent	Sodium Chloride 0.9% w/v
	Volume	140mg to 260mg in 250ml (264ml to 276ml including addition volume) 270mg to 560mg in 500ml (527ml to 556ml including addition volume) doses greater than or equal to 570mg in 1000ml (1057ml or greater including addition volume)
	Final container	Non-PVC e.g. polyolefin infusion bag with additive port cover. *Ideally infusion bag design will incorporate self sealing giving port to minimise H&S risks associated with accidental spillage during administration.*
	Starting materials	Licensed Thiotepa powder for reconstitution for injection Licensed Water for Injections Licensed Sodium Chloride 0.9% w/v Infusion bags
	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).

Thiotepa xxxmg
in xxxml Sodium Chloride 0.9% w/v
For Intravenous Infusion
Infuse the entire contents of the bag
Check the solution is free from particles before administering

Store in a Refrigerator at 2-8^{O}C 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