

### Product specification: Cladribine 500ml infusion bags

Name of product	Cladribine infusion. Aseptically prepared from licensed sterile starting materials.
Concentration	Concentration range typically up to 0.02mg/ml in 500ml infusion bags in accordance with the national dose banding tables. The Cladribine 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 accommodate the total dose.
Diluent	Sodium Chloride 0.9% w/v
Volume	500ml
Final container	Non-PVC e.g. polyolefin infusion bag with additive port cover. <i>Ideally infusion bag design will incorporate self sealing giving port to minimise H&amp;S risks associated with accidental spillage during administration.</i>
Starting materials	Licensed Cladribine (Leustat®) 1mg/ml solution for injection 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. Tall Man lettering must be used for the drug name. NB: The brand name must be included on the label to distinguish from the syringe product.
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):- <div style="border: 1px solid black; padding: 10px; text-align: center; margin: 10px auto; width: 80%;"> <p>cLADribine (Leustat®) xxmg 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</p> <p>Store in a Refrigerator at 2-8°C    Protect From Light Expiry: dd/mm/yyyy                      BN: XXXXXXXXX Keep out of the reach and sight of children Manufacturer's details                      MS XXXXXX <i>Caution Cytotoxic: Handle with care</i></p> </div>
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).