

Product specification: Cetuximab 500ml infusion bags

Name of product	Cetuximab infusion. Aseptically prepared from licensed sterile starting materials.								
Concentration	Concentration range typically up to 4mg/ml in 500ml infusion bags in accordance with the national dose banding tables. The Cetuximab 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 is suitable for all but the most extreme doses								
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&S risks associated with accidental spillage during administration.</i>								
Starting materials	Licensed Cetuximab 5mg/ml (Erbixux® or Biosimilar) concentrate solution for infusion. 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 e.g. brand leader or subsequent biosimilars must be included on the label.								
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; margin: 10px auto; width: fit-content;"> <p style="text-align: center;">CETUXimab (Brand Name) xxxmg in xxxml Sodium chloride 0.9% w/v For Intravenous Infusion Infuse the entire contents of the bag</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Store at Room Temperature</td> <td style="width: 50%;">Protect From Light</td> </tr> <tr> <td>Expiry: dd/mm/yyyy</td> <td>BN: XXXXXXXXX</td> </tr> <tr> <td colspan="2" style="text-align: center;">Keep out of the reach and sight of children</td> </tr> <tr> <td>Manufacturer's details</td> <td>MS XXXXXX</td> </tr> </table> </div>	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
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Keep out of the reach and sight of children									
Manufacturer's details	MS XXXXXX								
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	The stability study should conform to the Standard Protocol for deriving and assessment of stability of Aseptic preparations (Biopharmaceuticals) published by the NHS Pharmaceutical QA Committee (3rd Edition, April 2017).								