

Following a Rapid Alert Notification of a Quality Defect issued by the French Regulatory authorities AFSSAPS (France) and consultation with the local representative it was decided to recall all batches of Amsidine 75mg ampoules, solution for infusion.

The recall is being carried out because of external contamination at the base of certain ampoules in a particular batch with new information confirming a potential contamination on other batches justifying the withdrawal of all the batches. This defect does not affect the quality of the contents of the ampoules but it can involve the accidental exposure of the personnel by the product.

A new presentation Amsalyo is now available and a replacement process is currently ongoing through the local representative.

Drug Alert

CLASS 2 MEDICINES RECALL

Date: 3rd June 2004

Our Ref: MDR 5-5/04

**Amsidine 75mg ampoules, solution for infusion
(amsacrine)**

MA Number:5619804

Batch Number	Expiry Date	Pack Size	First Distributed
All batches			

For more information please contact:

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