

12th April 2011

Urgent Medicine Recall
Lasix[®] High Dose solution for infusion 250mg/25ml
(Frusemide)
AUST R 12408

Batch number	Expiry
0F009A	01/2014
0F040A	07/2014
40C331	03/2013
40C332	03/2013
40C360	08/2013
40U201	12/2011
40U230	06/2012
40U231	06/2012
40U248	09/2012
40U251	09/2012

Dear Pharmacist/Chief Pharmacist,

Sanofi-aventis australia pty ltd is initiating a recall of the Lasix[®] High Dose solution for infusion 250mg/25ml batches listed above. The recall is based upon our manufacturer's observation of a small amount of visible product-related particles in some ampoules of a limited number of batches of Lasix High Dose solution for infusion 250mg/25ml. This finding has been made during routine tests of the retention samples at the end of shelf life. No product technical complaint has been received by sanofi-aventis and no safety signals have been identified to date related to the presence of particles.

As a precautionary measure, sanofi-aventis, in agreement with the relevant Health Authorities, has decided to recall the affected batches of Lasix High Dose solution for infusion 250mg/25ml. Batches not covered by the recall may continue to be used as normal.

It has also been decided to reduce the shelf-life of Lasix High Dose solution for infusion 250mg/25ml from the current 4 years to 18 months. New batches with the reduced shelf-life will be manufactured and distributed as soon as possible.

The other injectable dosages of Lasix (20mg/2ml and 40mg/4ml) for which the formulation is slightly different are unaffected by this recall. Guidance for use of Lasix (20mg/2mL and 40mg/mL) in place of Lasix High Dose is available in the corresponding Product Information Leaflet.

This recall is being conducted with the knowledge and authority of the Therapeutic Goods Administration.

It is important that you carefully follow these recall instructions in relation to the return of the relevant batch numbers:

1. Further distribution of the batches of Lasix High Dose 250mg/25mL listed above should cease immediately.
2. Pharmacies should return all inventory with the affected batch numbers they have on hand to the wholesaler who initially supplied the product to them. The wholesaler will arrange for a credit. Please be certain to carefully review your batch numbers and return only the batches listed above. Only product from the above batch numbers will be accepted. Please complete the attached Lasix High Dose 250mg/25mL Recall Summary Document and fax it to sanofi-aventis australia Pty Ltd Customer Service on fax number no: 1800 647 467. Please note that other Lasix preparations are not impacted. Pharmacies should not return any product directly to sanofi-aventis australia Pty Ltd.
3. If you have no stock on hand for any of these batches please complete the attached Lasix High Dose 250mg/25mL Recall Summary Document and fax it to sanofi-aventis australia Pty Ltd Customer Service on fax number no: 1800 647 467 or email: productrecall.anz@sanofi-aventis.com.

Please ensure that all returns are actioned no later than 31st May 2011.

You should place an order immediately with your wholesaler for all replacement inventory you require. Please then continue to order in the normal manner all ongoing requirements of this product. Your wholesaler will have sufficient stock of Lasix High Dose 250mg/25mL compliant with the revised expiry date to re-supply.

If you have any questions about this recall of a medical nature, please call sanofi-aventis Medical Communications at 1800 818 806. If you have questions regarding returning stock or affected batch details please call sanofi-aventis product recall on 1800 152 416 (9:00 a.m. to 5:00 p.m. Eastern Standard Time). We regret any inconvenience and appreciate your immediate cooperation

Regards,



Dr Alex Condoleon
Medical Director
Sanofi-aventis australia Pty Ltd

Lasix High Dose 250mg/25mL RECALL SUMMARY DOCUMENT

TO: SANOFI-AVENTIS AUSTRALIA PTY LTD
CUSTOMER SERVICE DEPARTMENT
12-24 TALAVERA RD, BUILDING D (Do not send physical product back to this address)
MACQUARIE PARK
NEW SOUTH WALES 2113

FAX NO: 1800 647 467

FROM:
(Name of organisation)

CONTACT PERSON:
(Please print)

TELEPHONE NO:

FAX NO:

- We confirm that we **DO NOT** have any of Lasix High Dose 250mg/25mL with batch numbers 0F009A, 0F040A, 40C331, 40C332, 40C360, 40U201, 40U230, 40U231, 40U248, 40U251 in stock.
- We confirm that we have **RETURNED** all stock of Lasix High Dose 250mg/25mL with batches numbers 0F009A, 0F040A, 40C331, 40C332, 40C360, 40U201, 40U230, 40U231, 40U248, 40U251 to the wholesaler that provided us with the stock.

Signature: _____

Position: _____

Date: _____