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Important Safety Information

Dusseldorf, 14 November 2013

Recall due to Product defect of Oncaspar® injection solution (5ml vials with injection solution), approval number 30204.00.00

Affected batches:

ON3007D1, ON3007X2, ON3008D1, ON3008X2, ON3009X2, ON3010D1, ON3010X2

Due to a potential quality defect, sigma-tau Arzneimittel GmbH and sigma-tau Rare Diseases have decided to recall the complete Oncaspar® injection solution batches listed above.

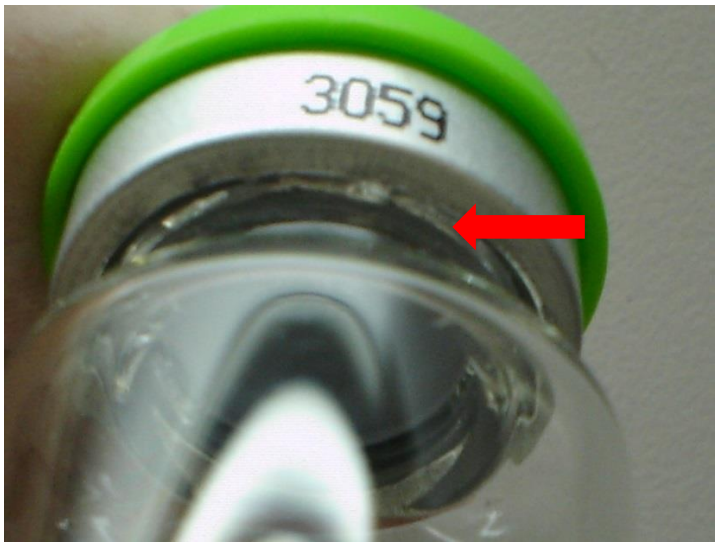
Both companies have been informed by sigma-tau PharmaSource Inc, Indianapolis, the bulk manufacturer of the Oncaspar® injection solution, of the potential for vials of the above mentioned batches to have fine cracks at the upper area of the bottle neck below the crimp cap which might result in leakage (assumed incidence: 1 in 5,000 injection vials). Due to the fine cracks, a microbial contamination of the solution is possible which could pose a risk of infection to patients. Although only one cracked vial was observed, as a precautionary measure the immediate recall of the above mentioned batches is being conducted.

The delivery of the affected batches of Oncaspar® injection solution has been stopped. Although sigma-tau Arzneimittel GmbH is currently working around the clock to provide replacement products, **it will still take about two weeks until being available for delivery.**

If an alternative treatment is not available and if the treatment with Oncaspar® injection solution is mandatory, the above mentioned batches of Oncaspar® injection solution can be used but only for individual cases and with utmost care. In such cases prior to use, the Oncaspar® injection vials must be visually checked for possible leakage and in particular for cracks at the upper area of the bottle neck below the crimp cap. If possible and if appropriate tools are available, the crimp cap should be removed in such cases in order to detect hidden cracks. Only use vials without cracks and leakages. As an additional safeguard, we recommend using bacteria-repelling filters such as sterile filters made

of PVDF (polyvinylidene fluoride) which must be integrated in the infusion systems when using vials from the above mentioned batches.

The following picture shows a possible defect directly below the crimp cap.



For **medical questions**, please contact the Medical Affairs department at +49 - (0) 2 11 - 68 77 170, or by e-mail at Oncasparmedical@sigma-tau.de

Adverse drug experiences should be reported to sigma-tau Rare Diseases S.A. at +351 291 203 070 or by e-mail at safety@sigmatau-rarediseases.com

For any **other questions about the recall**, please call Dr. Bimpe Adejuyigbe, Recall Coordinator at +44 7551 156200 , or by e-mail at bimpe.adejuyigbe@sigma-tau.co.uk

Please check your inventory and return any of the affected batches under **"uncooled conditions"** to our logistics provider:

KOMTUR Pharmaceuticals
Am Flughafen 6
79108 Freiburg

We apologize for any inconvenience.

Sincerely,

sigma-tau Arzneimittel GmbH

Dr. Christopher Friedel
Managing Director

PLEASE EMAIL COMPLETED INVENTORY FORM
to orders@sigma-tau.de or Fax: +49-89-55066 7525

RE: Product defect of Oncaspar® injection solution (5ml vials with injection solution)

INVENTORY FORM

Lot no	Quantity remaining at the time of notification (indicate "0" if none in inventory)
0N3007D1	
0N3007X2	
0N3008D1	
0N3008X2	
0N3009X2	
0N3010D1	
0N3010X2	

This is to certify that an inventory for vials from ONCASPAR® lots ON3007D1, ON3007X2, ON3008D1, ON3008X2, ON3009X2, ON3010D1 and ON3010X2 has been performed at the referenced facility. Set forth above is the number of vials of ONCASPAR® on hand at this facility on the date of receipt of the Product Recall Notification (Product defect of Oncaspar® injection solution) from Sigma-Tau Rare Diseases S.A.

We will not use, distribute, or otherwise dispose of these remaining vials of lots ON3007D1, ON3007X2, ON3008D1, ON3008X2, ON3009X2, ON3010D1 and ON3010X2, except as described herein. We will return any of these remaining vials as by sigma-tau Rare Diseases S.A.

Instructions: Please return any remaining lots under **"uncooled conditions"** or request product replacement to your distributor **KOMTUR Pharmaceuticals, Am Flughafen 6, 79108 Freiburg**

We understand that sigma-tau Arzneimittel GmbH, at its expense, will replace or refund any returned vials from these affected lots.

Name and Title (Printed):_____

Phone & Fax Number(s):_____

Email Address: _____

Facility:_____

Signature: _____Date: _____