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***Please forward to the enduser of this product!***

28 August 2018

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## **Urgent Field Safety Notice**

**ClinRep<sup>®</sup> Complete Kit for Antiepileptics in Serum / Plasma with UHPLC,  
order no. 14100**

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Dear customer,

this message contains an important safety information regarding the UHPLC analysis of lamotrigine with the ClinRep<sup>®</sup> Complete Kit for Antiepileptics with order no. 14100.

### **Description of the problem and associated risks:**

In a customer feedback a so far unknown interference with the lamotrigine peak was detected during co-medication with the following pharmaceuticals (active substances in brackets):

Antra Mups 20 mg (Omeprazol), Nexium 10 mg (Esomeprazol), Prograf 1 mg (Tacrolimus), Decostriol 0,5 (Calcitriol; 1,25 Dihydroxyvitamin D3) Midazolam-Hamelin 5 mg (Midazolam), L-Thyroxin 25 (L-Tyroxin), Tavor 2,5 (Lorazepam).

The observed co-elution of the interfering compound leads to significant false-high lamotrigine values in the toxic range with the risk of an insufficient medication for the patient.

### **Advice on action to be taken by the user:**

Please make sure the analysis requirements for lamotrigine are adapted according to the a.m. medications. In case one of these pharmaceuticals is included, the measuring results are not to be released.

**Transmission of this Field Safety Notice:**

Please inform all persons in your organisation who need to know of this information.

The competent authority (BfArM) has received a copy of this information.

With the enclosed form please confirm the receipt and distribution of this safety information.

**Safety measures taken by the manufacturer (RECIPE)**

As part of our complaint management process, initial interference examinations have already been performed. RECIPE will carry out further tests and investigations with respect to the above described potential interfering drug compounds. Within the next few weeks you will receive a separate notice with the findings of these examinations.

We would like to apologise for all inconveniences and thank you in advance for your cooperation. Please contact us for any further information.

Contact Person:

Dr. Carmen Alt  
Head of Customer Service, PMS

Telefon: +49 89 547081-14  
E-Mail: [alt@recipe.de](mailto:alt@recipe.de)

Yours sincerely



Dr. Stefan Plank  
Head of Regulatory Affairs / QM

**Confirmation of Receipt / Declaration for**

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**Urgent Field Safety Notice**

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order no. 14100**

**dated 28 August 2018**

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**Customer-related data**

Hospital / Laboratory	
Signature Head of Laboratory (Name)	
Address	
Phone	
Client ID	

**Confirmation of Receipt / Declaration**

I have read and understood the a.m. „Urgent Field Safety Notice“.  
All users of this product were also informed.

Date, signature: \_\_\_\_\_

We kindly ask to return this form by email ([customerservice@recipe.de](mailto:customerservice@recipe.de)) or fax (+49 89 547081-11) before **7 September 2018**.