

# D R U G   A L E R T

## CLASS 4 MEDICINES DEFECT INFORMATION

**Caution in Use  
Distribute to Pharmacy Level**

Date: 30 March 2015

EL (15)A/02

Our Ref: MDR 09-03/15

Dear Healthcare Professional,

### **Aventis Pharma Limited**

#### **Epilim 200mg Gastro-resistant Tablets, PL 04425/0302, Sanofi Livery**

Batch Number	Expiry Date	Pack Size	First Distributed
J601	Aug 2016	1 x 100	23 Oct 2014
J602	Aug 2016	1 x 100	12 Nov 2014
J603	Aug 2016	1 x 100	03 Dec 2014
K1	Jun 2017	1 x 100	29 Dec 2014
K2	Sep 2017	1 x 100	09 Jan 2015
K3	Sep 2017	1 x 100	06 Feb 2015
K7	Sep 2017	1 x 100	05 Jan 2015

#### **Epilim 500mg Gastro-resistant Tablets, PL 04425/0303, Sanofi Livery**

Batch Number	Expiry Date	Pack Size	First Distributed
J602	Aug 2016	1 x 100	19 Dec 2014
J603	Aug 2016	1 x 100	06 Jan 2015
K1	Jun 2017	1 x 100	22 Jan 2015
K2	Jun 2017	1 x 100	06 Feb 2015

### **Winthrop Pharmaceuticals UK Limited**

#### **Sodium Valproate Zentiva 200mg Gastro-resistant Tablets, PL 17780/0453, Zentiva Livery**

Batch Number	Expiry Date	Pack Size	First Distributed
K1	Jun 2017	1 x 100	02 Oct 2014

#### **Sodium Valproate Zentiva 500mg Gastro-resistant Tablets, PL 17780/0454, Zentiva Livery**

Batch Number	Expiry date	Pack Size	First Distributed
J601	Aug 2016	1 x 100	01 Oct 2014

We have been made aware of an unusual odour associated with the above batches of Epilim / Sodium Valproate Gastro-resistant tablets. The odour has variously been described as 'fishy', 'sweaty armpits'

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and 'cannabis'. An investigation by Sanofi has identified the root cause as the aluminium foil used in the packaging of affected batches. No impact on the quality or efficacy of the tablets has been detected. Sanofi has now ceased using this foil supplier.

In order to avoid product shortages which could impact on current advice not to switch between different manufacturers for this product, the above batches are not being recalled. Patients should therefore be advised to continue taking their medication. It may be necessary to distribute additional batches packed in the same foil in order to keep the market supplied. Batches packed in foil sourced from an alternative supplier are expected to be available by the end of April 2015 and distribution of impacted batches will cease at this time.

For all enquiries about this matter, please contact Sanofi Medical Information on 0845 3727101 or email [UK-medicalinformation@sanofi.com](mailto:UK-medicalinformation@sanofi.com)

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

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