



Department of
Health

An Roinn Sláinte

Máinnystrie O Poustie

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For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, HSC Board & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
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Our Ref: PHC/11/2021

Date: 04 May 2021

**MEDICINES NOTIFICATION
CLASS 4 MEDICINES DEFECT INFORMATION**

**Caution in Use
Distribute to Pharmacy/Wholesaler Level**

Dear Healthcare Professional

Lupin Healthcare (UK) Limited

Syonell 250mg Gastro-Resistant Tablets

PL 35507/0191

Batch Number	Expiry Date	Pack Size	First Distributed
G908002	Sep-21	30	06/01/2020
G908614	Oct-21	30	08/04/2020
G908561	Oct-21	30	20/03/2020
G003139	Mar-22	30	18/06/2020
G003899	Apr-22	30	25/09/2020
G003900	Apr-22	30	05/10/2020
G003901	Apr-22	30	04/02/2021

The following batches have been packed and are awaiting distribution:

Batch Number	Expiry Date	Pack Size	First Distributed
G004456	May-22	30	-
G004457	May-22	30	-

Syonell 500mg Gastro-Resistant Tablets

PL 35507/0192

Batch Number	Expiry Date	Pack Size	First Distributed
G908022	Sep-21	30	27/12/2019
G908441	Oct-21	30	09/03/2020
G908835	Oct-21	30	15/03/2020
G000647	Dec-21	30	20/03/2020

G000648	Dec-21	30	05/04/2020
G002361	Feb-22	30	11/05/2020
G002362	Feb-22	30	12/05/2020
G002363	Dec-21	30	28/05/2020
G002901	Mar-22	30	18/06/2020
G004160	Apr-22	30	24/09/2020
G004161	Apr-22	30	27/09/2020
G004168	Apr-22	30	26/10/2020
G004169	Apr-22	30	08/12/2020
G004170	Apr-22	30	01/02/2021
G004171	Apr-22	30	09/03/2021
G004931	May-22	30	11/01/2021

The following batches have been packed and are awaiting distribution:

Batch Number	Expiry Date	Pack Size	First Distributed
G004936	May-22	30	-
G004938	May-22	30	-
G004940	May-22	30	-
G004941	May-22	30	-
G004932	May-22	30	-
G004933	May-22	30	-

Active Pharmaceutical Ingredient: valproate semisodium

Brief description of the problem

Lupin Healthcare (UK) Limited has informed us of a discrepancy with the product packaging for several batches of Syonell 250mg Gastro-Resistant Tablets and Syonell 500mg Gastro-Resistant Tablets. This discrepancy relates to the incorrect amount of active pharmaceutical ingredient (valproate semisodium) printed on the outer packaging.

Labelling on the current packaging	Correct labelling on the packaging
<u>Syonell 250mg Gastro-Resistant Tablets</u> Each gastro-resistant tablet contains 250mg of valproate semi sodium	<u>Syonell 250mg Gastro-Resistant Tablets</u> Each gastro-resistant tablet contains 269.06mg of valproate semisodium equivalent to 250mg of valproic acid
<u>Syonell 500mg Gastro-Resistant Tablets</u> Each gastro-resistant tablet contains 500mg of valproate semi sodium	<u>Syonell 500mg Gastro-Resistant Tablets</u> Each gastro-resistant tablet contains 538.12mg of valproate semisodium equivalent to 500mg of valproic acid

The amounts of active pharmaceutical ingredient are stated correctly in the respective Patient Information Leaflets (PIL) and Summary of Product Characteristics (SmPCs).

Advice for healthcare professionals

Healthcare professionals are advised to exercise caution when dispensing the product. There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled.

Further Information

For more information or medical information queries, please contact: +44 (0) 1565 751 378 Option 1 or Pharmacovigilance Department at EU-PV@lupin.com

For stock control queries, please contact: 44 (0) 1565 751 378 Option 2 or information@lupin.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and dispensing General Medical Practitioners directly.

Yours sincerely



Mrs Cathy Harrison
Chief Pharmaceutical Officer