



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

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

Date: 06 December 2023

EL(23)A/42

Our Ref: MDR 055-11/23

Dear Healthcare Professional,

### Strandhaven Ltd t/a Somex Pharma

**Clarithromycin 250mg film-coated tablets**

**PL 15764/0039**

**SNOMED Code** 17522411000001102

Batch Number	Expiry Date	Pack Size	First Distributed
ET207E2001	Nov-25	14	14/09/2022
ET207E3001	Jun-26	14	08/02/2023
ET207E3002	Aug-26	14	08/05/2023
ET207E3003	Dec-26	14	15/09/2023

Active Pharmaceutical Ingredient: Clarithromycin

**Clarithromycin 500mg film-coated tablets**

**PL 15764/0040**

**SNOMED Code** 17522611000001104

Batch Number	Expiry Date	Pack Size	First Distributed
ET208E1001	Dec-24	14	05/06/2021
ET208E1002	Dec-24	14	01/04/2021
ET208E1003	Dec-24	14	01/04/2021
ET208E1004	Dec-24	14	01/04/2021
ET208E1005	Dec-24	14	05/06/2021
ET208E2001	Dec-25	14	13/05/2022
ET208E2002	Dec-25	14	13/05/2022
ET208E2003	Dec-25	14	24/05/2022
ET208E2005	Jan-26	14	13/05/2022
ET208E2004	Jan-26	14	08/07/2022
ET208E2006	Jan-26	14	08/07/2022
ET208E2007	Apr-26	14	11/08/2022
ET208E2008	Apr-26	14	11/08/2022
ET208E2009	Apr-26	14	11/08/2022
ET208E2010	Jul-26	14	18/11/2022
ET208E2011	Jul-26	14	18/11/2022
ET208E2012	Jul-26	14	18/11/2022
ET208E2013	Aug-26	14	18/11/2022



ET208E2014	Aug-26	14	18/11/2022
ET208E2015	Aug-26	14	14/12/2022
ET208E2016	Sep-26	14	14/12/2022
ET208E2017	Sep-26	14	14/12/2022
ET208E2018	Sep-26	14	14/12/2022
ET208E2019	Oct-26	14	09/01/2023
ET208E2020	Oct-26	14	09/01/2023
ET208E2021	Nov-26	14	08/02/2023
ET208E2022	Nov-26	14	08/02/2023
ET208E3001	Dec-26	14	17/03/2023
ET208E3002	Dec-26	14	17/03/2023
ET208E3003	Jan-27	14	12/04/2023
ET208E3004	Jan-27	14	12/04/2023
ET208E3005	Jan-27	14	12/04/2023
ET208E3006	Feb-27	14	28/04/2023
ET208E3007	Feb-27	14	28/04/2023
ET208E3008	Mar-27	14	08/07/2023
ET208E3009	Mar-27	14	08/07/2023
ET208E3010	Mar-27	14	08/07/2023
ET208E3011	Mar-27	14	15/07/2023
ET208E3012	Mar-27	14	15/07/2023
ET208E3013	Apr-27	14	15/07/2023
ET208E3014	Apr-27	14	15/07/2023
ET208E3015	Apr-27	14	15/07/2023
ET208E3016	May-27	14	15/09/2023
ET208E3017	May-27	14	15/09/2023
ET208E3018	May-27	14	15/09/2023
ET208E3019	May-27	14	15/09/2023
ET208E3020	May-27	14	15/09/2023

Active Pharmaceutical Ingredient: Clarithromycin

### Brief description of the problem

Strandhaven Limited t/a Somex Pharma has informed the MHRA regarding an error with the Patient Information Leaflets (PILs) that have been packed in the listed batches of Clarithromycin 250mg and 500mg film-coated tablets. The PIL does not include the most up to date safety information as described below. The information missing from the PILs is included below:

### 2. What you need to know before you take Clarithromycin

Do not take Clarithromycin tablets, and tell your doctor if:

- you are taking a medicine containing lomitapide
- you have abnormally low levels of potassium or magnesium in your blood (hypokalaemia or hypomagnesaemia)

It is important to tell your doctor or pharmacist if you are taking any of the following medicines:

- Warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (used to thin your blood)



### **Advice for healthcare professionals**

There is no risk to product quality because of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing the products and where possible, provide an updated PIL. The updated PIL is available electronically and can be downloaded from the [Somex Pharma Website](#). If it is not possible to provide an updated PIL please advise patients of the missing information and discuss with them whether the medicine is suitable for them.

Strandhaven Limited t/a Somex Pharma has confirmed that all future batches will contain the correct PIL. Upon request, Strandhaven Limited t/a Somex Pharma will post hard copies of the updated PIL to wholesalers and pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information (see contact details below).

### **Advice for patients**

No action is needed from patients. This issue is about missing information on the Patient Information leaflets (PILs) in specific batches of Clarithromycin 250mg and 500mg film-coated tablets, an antibiotic used to stop the growth of bacteria that cause infections. The medication itself is not affected.

These products will have been prescribed and dispensed by the qualified healthcare professional(s) responsible for your care.

If you have concerns about a medicine you may be using, please contact your healthcare professional. Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA [Yellow Card scheme](#).

### **Further Information**

For more information, or medical information queries, contact: [regulatory@somexpharma.com](mailto:regulatory@somexpharma.com), tel: 020 8590 9399, choose option 3 or 4. For stock control queries, contact: [accounts@somexpharma.com](mailto:accounts@somexpharma.com), tel: 020 8590 9399, choose option 2.

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully  
**Defective Medicines Report Centre**  
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