



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 17 June 2024

EL (24)A/22

Our Ref: MDR 043-05/24

Dear Healthcare Professional,

Viatrix UK Healthcare Ltd

Oxcarbazepine Mylan 150 mg Film-Coated Tablets

PL 04569/0779

SNOMED Code 13437411000001102

Batch Number	Expiry Date	Pack Size	First Distributed
A4659	03/2026	50	29/02/2024
A4660	04/2026	50	Not yet distributed

Oxcarbazepine Mylan 300 mg Film-Coated Tablets

PL 04569/0780

SNOMED Code 13437611000001104

Batch Number	Expiry Date	Pack Size	First Distributed
N3560	02/2026	50	05/02/2024
A4705	02/2026	50	18/03/2024

Oxcarbazepine Mylan 600 mg Film-Coated Tablets

PL 04569/0781

SNOMED Code 13437811000001100

Batch Number	Expiry Date	Pack Size	First Distributed
M3556	12/2025	50	09/02/2024

Active Pharmaceutical Ingredient: Oxcarbazepine

Brief description of the problem

Viatrix UK Healthcare Limited has informed the MHRA that the Patient Information Leaflet (PIL) packaged in the above specified batches of Oxcarbazepine 150 mg, 300 mg & 600 mg Film-Coated Tablets do not contain the most up to date safety information. The affected sections of the PIL are summarised in Appendix 1 of this notification.



Medicines & Healthcare products Regulatory Agency

Advice for healthcare professionals

There is no risk to product quality because of this issue, therefore the affected batches are not being recalled. Due to supply considerations, batch A4660 that has yet to be distributed will not be repackaged with the updated PIL prior to distribution. Viatris UK Healthcare Ltd has confirmed that all future batches of the product will contain the updated PIL.

Healthcare professionals are advised to ensure that patients are aware of the updated safety information when dispensing the affected batches of product. Please provide a copy of the updated PIL and remind the patient to read the entire leaflet before taking the medicine. The electronic versions of the PIL are up to date and can be accessed via the following links:

[Oxcarbazepine Mylan 150 mg Film-coated Tablets - Patient Information Leaflet \(PIL\)](#)

[Oxcarbazepine Mylan 300 mg Film-coated Tablets - Patient Information Leaflet \(PIL\)](#)

[Oxcarbazepine Mylan 600 mg Film-coated Tablets - Patient Information Leaflet \(PIL\)](#)

Hard copies of the updated PIL can also be requested from Viatris UK Healthcare Ltd (see contact details below) so that current stock in the dispensary can be supplemented with the correct PIL.

Advice for patients

The medicine itself is not affected and patients do not need to take any action. Patients should continue to take medicines from these batches as prescribed by your healthcare professional.

Patients should be aware that the Patient Information Leaflet included in the packs of the above specified batches of medicines does not contain the most up to date safety information. The affected information is summarised in Appendix 1 of this notification. The up-to-date version of the Patient Information Leaflet can be accessed via the links above. Please read this before taking the medicine.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should be reported via the MHRA [Yellow Card scheme](#).

Further Information

For medical information and stock control queries please contact:

Viatris UK Healthcare Limited Medical Information at +44 (0)1707 853 000 (select option 1) or info.uk@viatris.com. Customer Services can be reached at +44 (0)1707 853 000 (select 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
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk



Appendix 1

Affected texts in the older PIL text and updated texts in the current-approved PIL (in bold)

Section	Affected texts in older PIL	Updated texts in current approved PIL
<p>Section 2. What you need to know before you take Oxcarbazepine Mylan</p> <p><u>Other medicines and Oxcarbazepine Mylan</u></p>	<p>Tell your doctor if you are taking, have recently taken or might take any other medicines, particularly any of the following medicines as they may interact with Oxcarbazepine Mylan:</p> <p>other anticonvulsant medicines such as phenobarbital, phenytoin, carbamazepine, lamotrigine and valproic acid.</p> <p>Your doctor may need to adjust the dosage of these medicines when they are given in combination with Oxcarbazepine Mylan. In combination with lamotrigine there is an increased possibility of side effects like nausea, drowsiness, dizziness and headache occurring</p>	<p>Tell your doctor if you are taking, have recently taken or might take any other medicines, particularly any of the following medicines as they may interact with Oxcarbazepine Mylan:</p> <p>other anticonvulsant medicines such as phenobarbitone, phenytoin, carbamazepine, lamotrigine and valproic acid. Your doctor may need to adjust the dosage of these medicines when they are given in combination with Oxcarbazepine Mylan. In combination with lamotrigine there is an increased possibility of side effects like nausea, drowsiness, dizziness and headache occurring</p>
<p>Section 2. What you need to know before you take Oxcarbazepine Mylan</p> <p><u>Driving and using machines</u></p>	<p>You should be aware that Oxcarbazepine Mylan can cause side effects like dizziness, drowsiness, balance or co-ordination problems, eye problems including double or blurred vision, low levels of sodium in the blood which can cause muscle weakness, reduced levels of consciousness, especially when starting treatment or increasing the dose which can influence your ability to drive or operate machines. Do not drive or operate machines if you experience such side effects.</p>	<p>Oxcarbazepine has a moderate influence on the ability to drive and use machines. You should be aware that Oxcarbazepine Mylan can cause side effects like dizziness, drowsiness, balance or co-ordination problems, eye problems including double or blurred vision, low levels of sodium in the blood which can cause muscle weakness, reduced levels of consciousness, especially when starting treatment or increasing the dose which can influence your ability to drive or operate machines. Do not drive or operate machines if you experience such side effects.</p>
<p>Section 3. How to take Oxcarbazepine Mylan</p> <p><u>Method of administration</u></p>	<p>Swallow the film-coated tablet with a glass of water with or without food. Do not crush or chew them. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.</p>	<p>Swallow the film-coated tablet with a glass of water with or without food. Do not crush or chew them. The score line is only there to help you break the tablet if you have difficulty swallowing it whole but cannot divide the tablet in equal half doses.</p>



Section 4 Possible side effects	<ul style="list-style-type: none">• “Lethargy” and “muscle twitching” are added as adverse drug reactions (ADRs) with a ‘rare’ frequency of occurrence.• The frequencies of occurrences of several other ADRs have been updated and summarised as below:	
ADR Frequencies of Occurrence in Section 4		
ADRs updated as “Uncommon”	ADRs updated as “Rare”	ADRs updated as “Common”
<ul style="list-style-type: none">• weight gain, tiredness, hair loss, muscle weakness, feeling cold (signs of under active thyroid gland).• fall• high blood pressure• hives• raised level of liver enzymes while taking Oxcarbazepine Mylan.	<ul style="list-style-type: none">• swollen face, lips, eyelids, tongue, throat or mouth, difficulty in speaking, swallowing and sudden signs of nettle rash with difficulty in breathing, shortness of breath, wheezing (signs of angioedema and anaphylactic reactions)• skin rash and/or fever which may be manifestations of DRESS (Drug Rash with Eosinophilia and Systemic Symptoms), AGEP (Acute Generalized Exanthematous Pustulosis)• tiredness, shortness of breath when exercising, looking pale, headache, chills, dizziness, frequent infections leading to fever, sore throat, mouth ulcers, bleeding or bruising more easily than normal, nose bleeds, reddish or purplish patches, or unexplained blotches on the skin (signs of a decrease in the number of blood platelets or decrease in the number of blood cells).• Lethargy, confusion, muscle twitching or significant worsening of convulsions (possible symptoms of low sodium levels in the blood due to inappropriate ADH secretion) (see Warnings and precautions)	<ul style="list-style-type: none">• trembling; coordination problems; involuntary movement of the eyes; anxiety and nervousness; depression, mood swing; rash.• feeling weak; memory loss/disturbances; difficulty concentrating; lack of emotion or motivation (apathy); agitated or other mood changes; confusion; blurred vision; disturbance in vision; diarrhoea or constipation, stomach (abdominal) pain; acne; hair loss; loss of co-ordination; weight increase; speech disorder.