Ref:03/2024/PLD
20 June 2024

Tegretol: Oral Suspension (OS) 100 mg/ 5ml, Temporary Stock-out

Dear Healthcare professional,

Novartis Pharma Services Inc, Representative Office, Malta in agreement with the Malta Medicines Authority would like to inform you of a temporary stock out for Tegretol Oral Suspension (OS) 100 mg/ 5ml.

Summary

- **Update regarding an imminent stock out for Tegretol Oral Suspension (OS) due to manufacturing constraints associated with the sorbitol content (an excipient used in the formulation of Tegretol OS)**
- **Tegretol immediate release and Tegretol prolonged release tablets are not impacted**
- **Update regarding reduction of maximum daily dose out for Tegretol Oral Suspension (OS)**

This is an important update regarding an imminent stock-out situation with Tegretol OS. There is no impact on the currently available Tegretol tablet formulations IR (immediate release) or PR (prolonged release) tablets. Therefore, patients requiring Tegretol OS should be switched to alternative oral formulations of Tegretol, such as IR or PR tablets, where possible. If the prescribing physician determines that it is not feasible, alternative treatments such as generic or other antiseizure medicines (ASM) can be considered, taking into account their availability and adherence to relevant local or international epilepsy treatment guidelines.

Background to the manufacturing constraints: The formulation of Tegretol OS incorporates sorbitol as one of the excipients. Novartis is currently facing challenges in sourcing sorbitol batches compliant with the appropriate specifications.

Patients taking Tegretol OS should adhere to prescribed therapy. However, in anticipation of the imminent stock out, and to maintain adequate seizure control, the patients may need to be switched to other available options as discussed below.

Switching from Tegretol OS to a different antiseizure medication: Abrupt withdrawal of Tegretol OS may precipitate seizures, therefore, dosing must be gradually reduced while simultaneously introducing the new ASM. The new ASM must be initiated at a low dose and gradually titrated upwards. During this titration period, the dosage of Tegretol OS should be gradually reduced to prevent any breakthrough seizures (Villanueva et al 2018). The maintenance dose of the new ASM should be determined based on clinical assessment. The transition to an appropriate alternative treatment should be carried out in accordance with the guidance provided by the treating physician as outlined in the approved local label or in accordance with the relevant local epilepsy treatment guidelines.

In this context, please consider the following: Novartis confirms that there is an imminent stock-out situation with Tegretol OS. While there is no impact on other Tegretol formulations such as (IR and PR tablets), patients receiving Tegretol OS would either require substitution to tablets or to other alternatives such as generics or other ASMs based on the treating physician's discretion, as applicable. Under all circumstances, it is essential to refer to the locally approved label for guidance on switching and adhere to the applicable local epilepsy treatment guidelines.

Novartis would like to also take the opportunity to inform health care providers about the update of the maximum daily dose of Tegretol OS to 1200 mg/day. Patients prescribed with doses of Tegretol OS above 1200 mg/day should be permanently switched to an appropriate alternative as described above.[1]

Call for reporting

Healthcare providers and patients are encouraged to report adverse reactions in accordance with the national spontaneous reporting system for Adverse Drug Reactions (ADRs). Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Malta Medicines Authority Post-licensing, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, or sent by email to: postlicensing.medicinesauthority@gov.mt. Please report the product name and relevant details.

Healthcare Professionals may also report any adverse events associated with the use of Tegretol Oral Suspension (OS) to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.novartis.com/report or by e-mail at drug_safety.malta@novartis.com

Company contact point

Company	Product Name	Email	Phone
Novartis Pharma Services Inc, Representative Office, Malta	Tegretol Oral Suspension	novartis.malta@novartis.com	+356 21222872

Yours faithfully,

Post-Licensing Directorate
Medicines Authority

Disclaimer
This Direct Healthcare Professional Communication has been submitted to you on behalf of Novartis Pharma Services Inc, Representative Office, Malta.

The MMA receives the relevant contact details from both the Medical Council and the Pharmacy Council. Should you wish to amend your details including address, you are asked to contact the Medical Council or Pharmacy Council directly, as may apply.

[1] *Villanueva V, Ojeda J, Rocamora RA, et al (2018) EPICON consensus: recommendations for proper management of switching to eslicarbazepine acetate in epilepsy. Neurologia (Engl Ed); 33(5):290-300.*