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25th July 2016

GLAXOSMITHKLINE:
ADVANCE NOTIFICATION OF TROBALT® DISCONTINUATION

Dear Healthcare Professional,

Trobalt® 50mg, 100mg, 200mg, 300mg, 400mg tablets (retigabine) – Global Product Discontinuation

GlaxoSmithkline (GSK) is advising Healthcare Providers that Trobalt® (retigabine) tablets (50mg, 100mg, 200mg, 300mg and 400mg) will no longer be commercially available after June 2017. GSK intends to discontinue the product permanently due to the very limited usage of the medicine and the continued decline in new patient initiation.

Therapeutic Indication

Trobalt® is indicated as adjunctive treatment of drug-resistant partial onset seizures with or without secondary generalization in patients aged 18 years or older with epilepsy, where other appropriate combinations with other medicinal products have proved inadequate or have not been tolerated.

Key Messages

- **Trobalt® will be discontinued from all markets in June 2017 for commercial reasons**
- **Healthcare Providers should therefore begin seeking alternative medicines for existing patients as soon as possible, and ensure that all patients are withdrawn from this medicine by the end of June 2017 at the latest**
- **Patients' treatment should be withdrawn with a gradual dose reduction over a period of at least 3 weeks, in accordance with the current prescribing information**
- **All patients should continue to receive safety monitoring in line with the local prescribing information whilst they remain on treatment with Trobalt®**
- **Given the planned product discontinuation, no new patients should now start treatment with Trobalt®**

Action Being Taken by GlaxoSmithKline

GSK is communicating this information to regulatory authorities and Healthcare Providers. GSK is working closely with our distributors to ensure the medicine remains available to existing patients for the next year, providing sufficient time for a treatment alternative to be identified and initiated, where appropriate.

Action required by Healthcare Providers

In view of the planned discontinuation of this medicine, Healthcare Providers are advised to start seeking an alternative anti-epileptic drug as soon as possible to replace Trobalt® where necessary. All patients will need to have had their Trobalt® treatment discontinued by the end of June 2017 at the latest. Healthcare Providers should not initiate any new patients on Trobalt®.

Further Information

All adverse events should be reported directly to GSK (Malta) Limited, 1, 1st floor, de la Cruz Avenue, Qormi, QRM 2458 (phone: 21238131). Any suspected adverse reaction and medication errors can also be reported via the national Adverse Drug Reactions (ADRs) reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt. When reporting please provide as much information as possible, including information about medical history, concomitant medications, onset and treatment dates.

Contact(s) for Further Information/Questions

For all questions, please contact: Ruth Gatt (Medical Manager) at GSK (Malta) Limited at 21238131.

Yours sincerely

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