GlaxoSmithKline: ADVANCE NOTIFICATION OF TROBALT® DISCONTINUATION

Date: 26/08/2016

Dear Healthcare Provider,

Title: 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begin seeking alternative medicines for existing patients as soon as possible, and ensure that all patients are withdrawn from this medicine by the end of June 2017 at the latest.
- Patients' treatment should be withdrawn with a gradual dose reduction over a period of at least 3 weeks, in accordance with the current prescribing information.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®.

UK/RET/0091/16 August 2016

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

The management of medicine-related side effects depends on healthcare providers and consumers reporting them.

Any serious or unexpected side effects or lack of efficacy/benefit in patients should be reported by email to **ukpharmasafety@gsk.com** or **www.mhra.gov.uk/yellowcard**.

Alternatively, you can speak to a Safety Advisor by calling 0800 221 441 (option 3).

Contact(s) for Further Information/Questions

For any additional information, please contact our Medical Information Department on 0800 221 441 (option2).

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UK/RET/0091/16 August 2016