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Retigabine (TROBALT®): risk of acquired vitelliform maculopathy

Date: April 2016

Dear healthcare professional,

Summary and recommendations:

- Acquired vitelliform maculopathy (AVM} has been diagnosed in some patients taking retigabine .
- Carry out a macular optical coherence tomography (OCT} test as part ofthe routine eye monitoring at baseline and at least every six months for patients taking retigabine.
- Review the updated physician's guide (including the section on "points to discuss with your patients"} for further guidance

Background:

A macular abnormality with features of vitelliform maculopathy usually diagnosed through macular OCT has been identified in some patients taking retigabine. The new adverse drug reaction of AVM has therefore been included in the prescribing information for retigabine. This is in addition to the risk of pigmentation (discolouration} of ocular tissue, including the retina, previously identified for retigabine.

We have updated the relevant section of the Physician's guide ("Points to discuss with your patients") to provide you further guidance. Please review the Physician's Guide as well as the "Warnings and Precautions" and "Adverse reactions" sections ofthe labelling information for retigabine for more details.

If you require copies of the Physician's Guide, please visit the electronic Medicines Compendium (eMC): https://www .medicines .org.uk/emc/medi cine/24527. If you would like to obtain hard copies, these can be requested from medical information: telephone: .0800 221441 option 2 or email: ukmedo@gsk.com .

Please continue to report all suspected side effects to retigabine or any other medicine to the Medicines and Healthcare products Regulatory Agency (MHRA) through the Yellow Card scheme.

Please report:

- All suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- All suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/.

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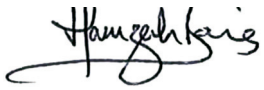
Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra .gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines {CHM) free phone line: 0800-731- 6789
- or by downloading and printing a form

Yours Sincerely



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