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Important Information for Healthcare Professionals

***Zovirax (aciclovir) 30 mg/g Eye Ointment (PA 1077/84/2)
Supply shortage due to quality issue.***

Dear Healthcare Professional,

GlaxoSmithKline (GSK), in agreement with the Health Products Regulatory Authority (HPRA), (formally known as The Irish Medicines Board) would like to inform you of the following:

Supply of Zovirax 30 mg/g Eye Ointment in Ireland will be significantly restricted over the next 6 months. This is as a result of a quality issue impacting batches of active pharmaceutical ingredient used in the manufacture of a number of batches of Zovirax Eye Ointment. The batches of active pharmaceutical ingredient were found to contain metal particles which were outside the upper specification limit for particle size. As a result of this issue, a number of batches of Zovirax Eye Ointment across the globe are being recalled and stock at the manufacturing site has been quarantined.

None of the affected batches of Zovirax Eye Ointment has been distributed on the Irish market and the recall action does not affect Irish batches. However, because of this issue, no alternative batches of this product are currently available and there will be an expected global shortage of Zovirax Eye Ointment until April 2015.

In Ireland, stock levels of Zovirax Eye Ointment are currently extremely low. GSK are supplying the product on a limited basis.

To ensure treatment is available as much as possible for patients where there is a clear clinical necessity, GSK is urging Healthcare Professionals to consider whether another antiviral product could be used instead, before prescribing or dispensing Zovirax eye ointment. Zovirax 30 mg/g Eye Ointment is indicated for the treatment of Herpes simplex keratitis. Oral valaciclovir is one of the alternatives to Zovirax eye ointment, but this is indicated for patients >12 years only.

Details on other potential treatments are available in the HPRA advisory statement at www.hpra.ie.

Company contact point

Further information can be obtained from:

GlaxoSmithKline (Ireland) Ltd., Stonemasons Way, Rathfarnham, Dublin 16

Freephone: 1800 244 255

GSK apologises for the inconvenience that this issue has caused and wish to ensure healthcare professionals and patients that GSK are doing all in our control to resolve this issue as soon as possible.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'S. McDonough', written in a cursive style.

Dr Stephen McDonough BM, BS, MRCP, MSc, FFPM

Medical Director UK and Ireland, GSK