

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level Recall

Date: 04 Nov 2014

EL (14)A/16

Our Ref: MDR 54-10/14

Dear Healthcare Professional,

The Wellcome Foundation Limited trading as GlaxoSmithKline UK

Zovirax Eye Ointment
(Aciclovir 3%)

PL 0003/0150

Batch Number	Expiry Date	Pack Size	First Distributed
3L942	Oct 2018	4.5G	10 Jan 2014
3M941	Jan 2019	4.5G	07 Apr 2014

GlaxoSmithKline UK is recalling the above batches of Zovirax Eye Ointment as a precaution because the batches of active pharmaceutical ingredient used in their manufacture were found to contain metal particles which were outside the upper specification limit for particle size. No complaints or adverse reaction reports relating to this issue have been received by the company to date.

Remaining stocks of the above batches should be quarantined and returned to the original supplier for credit. For enquiries relating to stock return please contact your original supplier.

There are no alternative batches of this product currently available and we understand that shortages are already being reported. Please find attached a copy of a Memo from UK Medical information (UKMI) advising on the availability of alternative therapies for the treatment of herpes simplex keratitis.

For medical information enquiries please contact GlaxoSmithKline Medical Information, tel: 0800 221 441 email: ukmedinfo@gsk.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

Alison Bunce

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Memo – shortage of supply

To:
From:
Date:

Re: Zovirax eye ointment 3%

Description of product affected

Zovirax eye ointment containing aciclovir 3%w/w (pack size 4.5g).¹

Why we are providing this information

In conjunction with the MHRA, GlaxoSmithKline UK is recalling some batches of Zovirax Eye Ointment as a precaution because the batches of active pharmaceutical ingredient used in their manufacture were found to contain metal particles which were outside the upper specification limit for particle size. GSK has confirmed that further supplies Zovirax Eye Ointment are unlikely to be available for several months and clinicians are going to need to identify alternative treatments for this condition.

Background

Zovirax eye ointment is licensed for the treatment of herpes simplex keratitis.¹

Herpes simplex eye infection is a sight-threatening condition.² It typically manifests as an herpetic keratitis and may involve any of the layers of the cornea. Epithelial keratitis accounts for most first episodes of herpes simplex keratitis, while stromal keratitis is unusual in initial disease but common in recurrent disease. The prognosis for visual loss is significantly worse for stromal than epithelial disease.

In primary care, all suspected acute cases of suspected herpes simplex should be urgently referred to the emergency eye service.³

Implications for patient care

Patients presenting with herpes simplex keratitis should be referred to an ophthalmologist as a matter of urgency.⁴ A sample is collected if an epithelial keratitis is present. This may also enable resistance testing if required. Currently treatment is commenced with either aciclovir 3% eye ointment or ganciclovir 0.15% eye gel, both 5 times a day without tapering.

In the absence of aciclovir eye ointment, treatment options are limited. In the USA, aciclovir eye ointment is not available, and the American College of Ophthalmology recommend topical administration of ganciclovir or trifluridine, or oral use of an antiviral such as acyclovir.^{2,5} These recommendations are in line with the findings of a systematic review published by the Cochrane Library, which found no significant differences in efficacy between topical aciclovir, topical ganciclovir, topical trifluridine and oral aciclovir for the treatment of herpes simplex keratitis.⁶

Management options

- ◆ The only other topical product that is currently licensed in the UK for herpes simplex keratitis is ganciclovir 0.15% eye gel (Virgan)⁷ – licensed for the treatment of acute herpetic keratitis (dendritic and geographic ulcers), given as one drop five times daily until epithelial healing occurs. Treatment should not exceed 21 days.
- ◆ A treatment course of oral aciclovir 400mg 5 times a day for 10 to 14 days.

- ◆ Aciclovir 3% eye ointment may be available as an imported medicine but approval for use would need to follow normal governance procedures for unlicensed medicines
- ◆ Trifluorothymidine 1% (trifluridine, Viroptic) [unlicensed] is given one drop every two hours (eight or nine doses daily). Full dosing for two weeks may be necessary to prevent early reactivation, but drops are often tapered after the first week. Treatment is limited by epithelial toxicity, especially when used for longer than three weeks. Trifluridine is manufactured by Stockport Pharmaceuticals.⁸ Again approval for use would need to follow normal governance procedures for unlicensed medicines

Choice of treatment will need to take account of supply chain stability, cost, and the clinical opinions of local ophthalmology department.

References

1. Zovirax eye ointment SPC (Date of revision = 13 December 2013)
<http://www.medicines.org.uk/emc/medicine/2187>
2. Lee White M and Chodosh J. Herpes simplex virus keratitis: A treatment guideline - 2014
<HTTP://ONE.AAO.ORG/ASSETS/6564936E-9929-48B6-93CD-15872A1B388E/635424082284100000/HSV-KERATITIS-TREATMENT-GUIDELINE-HARVARD-PDF>
3. Clinical Knowledge Summaries website (last revised September 2012)
<http://cks.nice.org.uk/herpes-simplex-ocular#!scenario>
4. The College of Optometrists (February 2012)
http://www.google.co.uk/url?url=http://www.college-optometrists.org/download.cfm/docid/DC03DA1E-4CD8-4BBA-AE99E36CA4E0E23&rct=j&frm=1&q=&esrc=s&sa=U&ei=X7VQVN3OFqSV7Aax4oGODw&ved=0CBQQFjAA&sig2=plBUYuneHX1fidKVX6L3Gg&usq=AFQjCNFbNCQqyd13uuHcnRWJ1XRcII_G_w
5. UpToDate.com (subscription required) http://www.uptodate.com/contents/herpes-simplex-keratitis?source=search_result&search=ocular+herpes&selectedTitle=1%7E14#H26
6. Wilhelmus K R. Antiviral treatment and other therapeutic interventions for herpes simplex virus epithelial keratitis. The Cochrane Library (26 October 2010)
<http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002898.pub4/abstract>
7. Virgan (ganciclovir) eye gel SPC (Date of revision = 16 July 2014)
<http://www.medicines.org.uk/emc/medicine/24747>
8. Personal communication, Stockport Pharmaceuticals – 29 October 2014

Acknowledgements

Moorfields Eye Hospital Medicines Information Department – personal communication on 28 October 2014.

Original document prepared by:

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Guy's and St Thomas' NHS Foundation Trust
31st October 2014

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