DRUG ALERT
CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 09 April 2019 EL (19)A/09 Our Ref: MDR 105-03/19

Dear Healthcare Professional,

Martindale Pharmaceuticals Limited

Chloramphenicol 0.5% W/V Antibiotic Eye Drops PL 00156/0109

Martindale Pharmaceuticals has informed us of two issues with all unexpired batches of the above product, PL 00156/0109, legal status ‘P’. The batch numbers are tabulated below:

<table>
<thead>
<tr>
<th>Batch Number 1</th>
<th>Batch Number 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1810248</td>
<td>1901208</td>
</tr>
<tr>
<td>1811060</td>
<td>1901756</td>
</tr>
<tr>
<td>1811129</td>
<td>1901757</td>
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<tr>
<td>1811249</td>
<td>1901759</td>
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<tr>
<td>1812309</td>
<td>1901854</td>
</tr>
<tr>
<td>1812310</td>
<td>1902375</td>
</tr>
<tr>
<td>1812583</td>
<td>1902389</td>
</tr>
<tr>
<td>1901163</td>
<td>1902418</td>
</tr>
<tr>
<td>1901164</td>
<td>1902601</td>
</tr>
</tbody>
</table>

Brief description of the problem

- The Braille is missing from the carton
- Packs contain the Patient Information Leaflet (PIL) for the product with legal status ‘POM’.

Advice for healthcare professionals

In order to maintain supply, the affected batches are not being recalled.

The content of the PIL for the ‘P’ version is similar to that for the ‘POM’ version but there are some differences in the way the information is expressed. The correct PIL for the ‘P’ product can be downloaded via the following link:

https://www.medicines.org.uk/emc/product/9662/pil
Further Information

For any enquiries please contact Martindale / Ethypharm Customer Services, email Licensed@ethypharm.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional Teams are asked to forward this to relevant clinics, community pharmacists and dispensing General Practitioners for information.

Yours faithfully

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