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Committee for Human Medicinal Products (CHMP)

Information for the package leaflet regarding phosphates used as excipients in eye drops

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Information for the package leaflet regarding phosphates used as excipients in eye drops

Executive summary

Phosphates are substances that are widely used in eye drops. In 2012 the Committee for Human Medicinal Products (CHMP) examined information from the manufacturers on different eye drop products and concluded that there was some evidence to suggest that patients who already had severe damage to the cornea might develop calcification during treatment with phosphate-containing eye drops. However, the CHMP considered that the benefits of the phosphate-containing eye drop medicines authorised in the EU outweigh their risks, and therefore recommended that they can continue to be used. Nonetheless, in order to make healthcare professionals and patients aware of the issue, it was recommended that the information for the package leaflet of eye medicines containing phosphates should be updated, as well as the Summary of Product Characteristics.

This document presents the wording recommended by CHMP in 2012 in a tabular format so that the Annex of the the European Commission guideline 'Excipients in the labelling and package leaflet of medicinal products for human use' (EMA/CHMP/302620/2017) is updated accordingly.

Scientific background

Please refer to the 'Questions and answers on the use of phosphates in eye drops' (EMA/CHMP/753373/2012) – [link](#).

New information in the package leaflet

Name	Route of Administration	Threshold	Information for the Package Leaflet	Comments
Phosphate buffers	Ocular	Zero	<p>This medicine contains x mg phosphates in each <dosage unit><unit volume> <which is equivalent to x mg/<weight><volume>>.</p> <p>If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.</p>	<p>Corresponding SmPC statement in Section 4.8 (Undesirable effects):</p> <p>“Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.”</p>