

## **Cosopt preservative-free eye drops: new interim container**

Cosopt preservative-free, single-dose eye drops contain dorzolamide and timolol and are used to treat glaucoma.

### **Brief description of the problem**

We are aware of 69 complaints in the UK with this product following the introduction of a new design of dropper with a winged tip in July 2013. The wings and the pieces of plastic that stay on the dropper tip after opening can make it difficult to use and increase the risk of eye injury. A Drug Safety Update article was issued on 5 December 2013 to make healthcare professionals aware of this problem. (see [Dorzolamide hydrochloride/timolol maleate \(Cosopt\) preservative-free single-dose eye drops: reports of eye injury](#))

This has been followed up with a letter sent to healthcare professionals on 27 January 2014.

[Cosopt® Preservative Free Eye Drops: Important Change to Pipette Design](#)  (167Kb)

### **New container – an interim measure**

Merck Sharp & Dohme will be replacing this container with a new design which will be available from 10 February 2014 as an interim measure.

### **New instructions for patients on how to put the drops into the eye**

Due to technical reasons, the patient information leaflet which will be supplied with the new Cosopt container will still contain information on the previous design. To ensure that patients have up to date information we are publishing a supplementary, up-to-date patient information leaflet and detailed instructions for using the new eye drop container here:

[Supplementary, up-to-date patient information leaflet](#)  (1012Kb)

[Detailed instructions for use](#)  (779Kb)

### **Review by the Commission on Human Medicines**

The current winged container and the new container have been reviewed by Commission on Human Medicines and its Expert Advisory Groups. The Commission considers the new container to be an improvement however concerns remain about it as a permanent replacement because it still has some of the design features of the previous container. The Commission was informed that if both old and new versions of the container were unavailable, there would be insufficient supplies of alternative preservative free medicine to meet patient demand. The Commission therefore accepted the MHRA's proposal to allow release of Cosopt in the new container as an interim measure to ensure adequate supplies of this medicine for patients.

The current winged container will be withdrawn from the market at the same time as the new container is introduced.

The following information is available:

#### **Minutes of the Commission on Human Medicines**

[14 November 2013](#) 

[12 December 2013](#) 

#### **Minutes of the Chemistry, Pharmacy and Standards Expert Advisory Group**

[15 October 2013](#) 

[12 November 2013](#) 

[10 December 2013](#) 

**Minutes of the Pharmacovigilance Expert Advisory Group**

[30 October 2013](#) 