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Committee for Medicinal Products for Human Use (CHMP)

# Ganfort

bimatoprost, timolol

Procedure no. EMEA/H/C/000668/PSUV/0020

Period covered by the PSUR: 20 September 2010 – 19 November 2012

## Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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**Scientific conclusions**

Taking into account the PRAC Assessment Report on the PSUR for Circadin, the scientific conclusions of PRAC are as follows:

The PRAC considered that the overall risk/benefit of GANFORT remained favourable.

However, the MAH was recommended that within section 4.8 of the SmPC, the following ADRs be moved from the tables for ADRs seen only with the individual components (timolol and bimatoprost) to the table for ADRs seen with GANFORT: Bronchospasm (predominantly in patients with pre-existing bronchospastic disease), dyspnea, eyelid retraction and dizziness.

In section 4.8 of the SmPC, the following wording should be added: “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.”

The above-mentioned SmPC changes will need to be reflected in the PL.

The CHMP agrees with the scientific conclusions made by the PRAC.

**Grounds recommending the variation to the terms of the Marketing Authorisation**

On the basis of the scientific conclusions for Ganfort the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing the two active substances bimatoprost and timolol is favourable subject to the proposed changes to the product information, as follows:

Update of section 4.8 of the SmPC

- The Safety information needs amending to reflect the available data. The following ADRs should be moved from the tables for ADRs seen only with the individual components (timolol and bimatoprost) to the ADR table for ADRs seen with GANFORT: Bronchospasm (predominantly in patients with pre-existing bronchospastic disease), dyspnea, eyelid retraction and dizziness.

- GANFORT contains a phosphate buffer as an excipient. In line with an assessment of the use of phosphate buffers in medicinal products given as eye drops, the following wording should be added: “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.”

The CHMP recommends that the terms of the Marketing Authorisation should be varied