

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Brimonidintartrat/Timolol “DOC Generici” (DK) and BRIMOCOMB (IT) (brimonidine/timolol)**

This is a summary of the risk management plan (RMP) for Brimonidintartrat/Timolol “DOC Generici” and BRIMOCOMB. The RMP details important risks of Brimonidintartrat/Timolol “DOC Generici” and BRIMOCOMB and how more information will be obtained about Brimonidintartrat/Timolol “DOC Generici” and BRIMOCOMB's risks and uncertainties (missing information).

Brimonidintartrat/Timolol “DOC Generici” and BRIMOCOMB's summary of product characteristics (SmPC) and package leaflet give essential information to healthcare professionals and patients on how Brimonidintartrat/Timolol “DOC Generici” and BRIMOCOMB should be used.

Important new concerns or changes to the current ones will be included in updates of Brimonidintartrat/Timolol “DOC Generici” and BRIMOCOMB's RMP.

#### **I. The medicine and what it is used for**

Brimonidintartrat/Timolol “DOC Generici” and BRIMOCOMB are authorised for reduction of intraocular pressure (IOP) in patients with chronic open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers. The products contain brimonidine and timolol as the active substances and they are taken by eye administration.

## **II. Risks associated with the medicine and activities to minimise or further characterise the risks**

Important risks of Brimonidintartrat/Timolol "DOC Generici" and BRIMOCOMB, together with measures to minimise such risks and the proposed studies for learning more about Brimonidintartrat/Timolol "DOC Generici" and BRIMOCOMB 's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Brimonidintartrat/Timolol "DOC Generici" and BRIMOCOMB is not yet available, it is listed under 'missing information' below.

### **II.A List of important risks and missing information**

Important risks of brimonidine/timolol are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of brimonidine/timolol. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

<b>List of important risks and missing information</b>	
Important identified risks	None
Important potential risks	None
Missing information	None

### **II.B Summary of important risks**

The safety information in the proposed Product Information is aligned to the reference medicinal product.

## ***II.C Post-authorisation development plan***

### **II.C.1 Studies which are conditions of the marketing authorisation**

There are no studies which are conditions of the marketing authorisation or specific obligation of Brimonidintartrat/Timolol "DOC Generici" and BRIMOCOMB.

### **II.C.2 Other studies in post-authorisation development plan**

There are no studies required for Brimonidintartrat/Timolol "DOC Generici" and BRIMOCOMB.