Part VI: Summary of the Risk Management Plan

Summary of risk management plan for COMBIGAN (brimonidine and timolol)

This is a summary of the RMP for COMBIGAN. The RMP details important risks of COMBIGAN and how more information will be obtained about risks and uncertainties (missing information).

COMBIGAN's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how COMBIGAN should be used.

Important new concerns or changes to the current ones will be included in updates of COMBIGAN's RMP.

I The Medicine and What it Is Used For

COMBIGAN is authorized for the reduction of IOP in patients with chronic OAG or OHT who are insufficiently responsive to topical beta-blockers (see SmPC for the full indication). It contains brimonidine 0.2% and timolol 0.5% as the active substances and it is given by eye drop BID.

II Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of COMBIGAN, together with measures to minimize such risks and the proposed studies for learning more about COMBIGAN's risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

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

II.A List of Important Risks and Missing Information

Important risks of COMBIGAN are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. 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 COMBIGAN. 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).

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

Not applicable.

II.C Post-Authorization Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorization

There are no ongoing studies which are conditions of the marketing authorization or specific obligation of COMBIGAN.

II.C.2 Other Studies in Post-Authorization Development Plan

There are no ongoing studies required for COMBIGAN.