

## Summary of risk management plan for Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution

This is a summary of the risk management plan (RMP) for Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution. The RMP details important risks of Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution., how these risks can be minimised, and how more information will be obtained about Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution risks and uncertainties (missing information).

Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution should be used.

Important new concerns or changes to the current ones will be included in updates of Bimatoprost/Timolol eyes drops RMP.

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

Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution are indicated for reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

It contains 0,3 mg of bimatoprost and 5 mg of timolol as the active substance and will be used ocular.

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

Important risks of Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution, together with measures to minimise such risks and the proposed studies for learning more about Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution 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 Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution is not yet available, it is listed under 'missing information' below.

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

Important risks of Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution are risks that need special risk management activities to further investigate or minimise 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 Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution. 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	<ul style="list-style-type: none"><li>• Iris hyperpigmentation</li><li>• Punctate keratitis</li><li>• Acute asthma and asthmatic symptoms</li><li>• Bradycardia</li><li>• Cystoid macular edema</li></ul>
Important potential risks	<ul style="list-style-type: none"><li>• Cardiovascular events (angina, hypotension, congestive heart failure)</li><li>• Choroidal detachment</li></ul>
Missing information	<ul style="list-style-type: none"><li>• Exposure in pediatric patients</li><li>• Exposure in pregnancy and lactation</li></ul>

## II.B Summary of important risks

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

<b>Important identified risk: Iris hyperpigmentation</b>	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC Section: 4.8, 4.4 Prescription only medicine

<b>Important identified risk: Punctate keratitis</b>	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC Section: 4.8, 4.4 Prescription only medicine

<b>Important identified risk: acute asthma and asthmatic symptoms</b>	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC Section: 4.3, 4.4, 4.8, 4.9 Prescription only medicine

<b>Important identified risk: Bradycardia</b>	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC Section: 4.3, 4.5, 4.8, 4.9 Prescription only medicine

<b>Important potential risk: Cystoid macular edema</b>	
Risk minimisation measures	<u>Routine risk minimisation measures</u> SmPC Section: 4.4, 4.8 Prescription only medicine

<b>Important potential risk: Cardiovascular events (angina, hypotension, congestive heart failure)</b>	
Risk minimisation measures	<u>Routine risk minimisation measures</u> SmPC Section: 4.3, 4.4, 4.8 Prescription only medicine

<b>Important potential risk: Choroidal detachment</b>	
Risk minimisation measures	<u>Routine risk minimisation measures</u> SmPC Section: 4.4, 4.8 Prescription only medicine

## ***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 Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution.

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

There are no studies required for Bimatoprost Timolol Zentiva 0.3 mg / ml + 5 mg / ml, eye drops solution.