

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

# Summary of risk management plan for Carteol (Carteolol Hydrochloride)

This is a summary of the risk management plan (RMP) for Carteol. The RMP details important risks of Carteol, and how more information will be obtained about Carteol's risks and uncertainties (missing information).

Carteol's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Carteol should be used.

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

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

Carteol is an eye drops containing carteolol hydrochloride as active substance and it is used to treat the elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension (see SmPC for the full indication).

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

Important risks of Carteol, together with measures to minimise such risks and the proposed studies for learning more about Carteol'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 way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.
- The medicine's legal status — Carteol is prescription-only, so the supply to patients is controlled, minimising the risks associated with incorrect use of the product.

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, 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 Carteol 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 Carteol. 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***

Not applicable. No safety concerns have been identified for Carteol.

## ***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 Carteol.

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

There are no studies required for Carteol.