NOVARTIS

Regulatory Affairs

Azopt®

Summary of the EU Safety Risk Management Plan

Active substance(s) (INN or common name):	brinzolamidum
Product(s) concerned (brand name(s)):	Azopt
Document status:	Final
Version number of the RMP Public Summary	1.0
Date of final sign off of the RMP Public Summary	14-August-2023

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of “Azopt” is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of “Azopt” in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Novartis Pharma Schweiz AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of “Azopt”.

Summary of the risk management plan for brinzolamide (Azopt)

This is a summary of the risk management plan (RMP) for Azopt. The RMP details important risks of Azopt, how these risks can be minimized, and how more information will be obtained about Azopt's risks and uncertainties (missing information).
Azopt's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Azopt should be used.
This summary of the RMP for Azopt should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Azopt is indicated to decrease elevated intraocular pressure in ocular hypertension and open-angle glaucoma as monotherapy in adult patients unresponsive to beta-blockers or in adult patients in whom beta-blockers are contraindicated, or as adjunctive therapy to beta-blockers or prostaglandin analogues. Azopt contains brinzolamide as the active substance and it is given as eye drops administered by topical ocular administration.

Further information about the evaluation of Azopt's benefits can be found in Azopt's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage*:* <ema.europa.eu/en/medicines/human/EPAR/azopt>.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Azopt, together with measures to minimize such risks and the proposed studies for learning more about Azopt '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 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 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 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 Azopt are risks that need special risk management activities to further investigate or minimize 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 Azopt. 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).

Table 13-1 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, since there are no important risks/safety concerns.

II C: Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

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

II.C.2. Other studies in post-authorization development plan

There are no studies required for Azopt.