

Part VI: Summary of the risk management plan

Summary of risk management plan for Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados (bilastine eye drops solution)

This is a summary of the Risk Management Plan (RMP) for Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Legonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados. The RMP details important risks of Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados, how these risks can be minimised, and how more information will be obtained about the risks of these products and uncertainties (missing information).

The Summary of Product Characteristics (SmPC) of Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados and their package leaflets give essential information to healthcare professionals and patients on how Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados should be used.

Important new concerns or changes to the current ones will be included in updates of Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados' RMP.

I. The medicine and what it is used for

Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados are intended for the treatment of ocular signs and symptoms of seasonal and perennial allergic conjunctivitis in adults and paediatric population aged 2 years and older (see SmPCs for the full indication). They contain bilastine as the active substance and are given by eye drops, solution formulation.

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

Important risks of Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados, together with measures to minimise such risks and the proposed studies for learning more about risks of these products, 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, 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 Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or 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 Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados. 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

No important risks have been described for Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados.

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 Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados.

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

There are no studies required for Antires, Ayrinal, Bellozal, Bilador, Bilargen, Bilaska, Bilaxten, Bilaz, Bitosen, Borenar, Clatra, Drynol, Gosall, Ibis, Ilaxten, Inorial, Lendin, Lergonix, Nixar, Olisir, Omarit, Opexa, Robilas, Xados.