
PART VI. : SUMMARY OF THE RISK MANAGEMENT PLAN**SUMMARY OF RISK MANAGEMENT PLAN FOR ALTEISDUO, BELSAR PLUS, CARDOSAL PLUS, CO-TENSIOL, HIPERSAR PLUS, IXIA PLUS, LARESIN PLUS, MENARTAN PLUS, MENCORD PLUS, MESAR PLUS, OLARTAN-PLUS, OLPREZIDE, OLSAR PLUS, OMESAR PLUS, PLAUNAZIDE, REVIVAL PLUS, SARTEN PLUS H, TENZAR PLUS, VOTUM PLUS, OLMETEC PLUS, OLMES PLUS
(OLMESARTAN MEDOXOMIL/HYDROCHLOROTHIAZIDE)**

This is a summary of the risk management plan (RMP) for Alteisduo, Belsar Plus, Cardosal Plus, Co-Tensiol, Hipersar Plus, Ixia Plus, Laresin Plus, Menartan Plus, Mencord Plus, Mesar Plus, Olartan-Plus, Olprezide, Olsar Plus, Omesar Plus, Plaunazide, Revival Plus, Sarten Plus H, Tenzar Plus, Votum Plus, Olmetec Plus, Olmes Plus.

The RMP details important risks of Alteisduo, Belsar Plus, Cardosal Plus, Co-Tensiol, Hipersar Plus, Ixia Plus, Laresin Plus, Menartan Plus, Mencord Plus, Mesar Plus, Olartan-Plus, Olprezide, Olsar Plus, Omesar Plus, Plaunazide, Revival Plus, Sarten Plus H, Tenzar Plus, Votum Plus, Olmetec Plus, Olmes Plus, 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 Alteisduo, Belsar Plus, Cardosal Plus, Co-Tensiol, Hipersar Plus, Ixia Plus, Laresin Plus, Menartan Plus, Mencord Plus, Mesar Plus, Olartan-Plus, Olprezide, Olsar Plus, Omesar Plus, Plaunazide, Revival Plus, Sarten Plus H, Tenzar Plus, Votum Plus, Olmetec Plus, Olmes Plus and their package leaflets give essential information to healthcare professionals and patients on how they should be used.

I. THE MEDICINE AND WHAT IT IS USED FOR

Alteisduo, Belsar Plus, Cardosal Plus, Co-Tensiol, Hipersar Plus, Ixia Plus, Laresin Plus, Menartan Plus, Mencord Plus, Mesar Plus, Olartan-Plus, Olprezide, Olsar Plus, Omesar Plus, Plaunazide, Revival Plus, Sarten Plus H, Tenzar Plus, Votum Plus, Olmetec Plus, Olmes Plus are authorised for treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled on OM alone (see SmPC for the full indication). They contain olmesartan medoxomil/hydrochlorothiazide as the active substances and they are given by oral formulations (20 mg/12.5 mg, 20 mg/25 mg, 40 mg/12.5 mg and 40 mg/25 mg film-coated tablets).

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of Alteisduo, Belsar Plus, Cardosal Plus, Co-Tensiol, Hipersar Plus, Ixia Plus, Laresin Plus, Menartan Plus, Mencord Plus, Mesar Plus, Olartan-Plus, Olprezide, Olsar Plus, Omesar Plus, Plaunazide, Revival Plus, Sarten Plus H, Tenzar Plus, Votum Plus, Olmetec Plus, Olmes Plus, 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 Alteisduo, Belsar Plus, Cardosal Plus, Co-Tensiol, Hipersar Plus, Ixia Plus, Laresin Plus, Menartan Plus, Mencord Plus, Mesar Plus, Olartan-Plus, Olprezide, Olsar Plus, Omesar Plus, Plaunazide, Revival Plus, Sarten Plus H, Tenzar Plus, Votum Plus, Olmetec Plus, Olmes Plus are risks that need special risk management activities to further investigate or minimise 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 Alteisduo, Belsar Plus, Cardosal Plus, Co-Tensiol, Hipersar Plus, Ixia Plus, Laresin Plus, Menartan Plus, Mencord Plus, Mesar Plus, Olartan-Plus, Olprezide, Olsar Plus, Omesar Plus, Plaunazide, Revival Plus, Sarten Plus H, Tenzar Plus, Votum Plus, Olmetec Plus, Olmes Plus. 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.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B. Summary of important risks

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

Important identified risk, potential risk or Missing information: None	
Evidence for linking the risk to the medicine	Not applicable
Risk factors and risk groups	Not applicable
Risk minimisation measures	Not applicable

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 Alteisduo, Belsar Plus, Cardosal Plus, Co-Tensiol, Hipersar Plus, Ixia Plus, Laresin Plus, Menartan Plus, Mencord Plus, Mesar Plus, Olartan-Plus, Olprezide, Olsar Plus, Omesar Plus, Plaunazide, Revival Plus, Sarten Plus H, Tenzar Plus, Votum Plus, Olmetec Plus, Olmes Plus.

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

There are no studies required for Alteisduo, Belsar Plus, Cardosal Plus, Co-Tensiol, Hipersar Plus, Ixia Plus, Laresin Plus, Menartan Plus, Mencord Plus, Mesar Plus, Olartan-Plus, Olprezide, Olsar Plus, Omesar Plus, Plaunazide, Revival Plus, Sarten Plus H, Tenzar Plus, Votum Plus, Olmetec Plus, Olmes Plus.