

Part VI: Summary of the risk management plan

Summary of risk management plan for Omega 3 Aurobindo 1000 mg capsule molli (Omega-3-Fatty Acid Ethyl Esters)

This is a summary of the risk management plan (RMP) for Omega 3 Aurobindo 1000 mg capsule molli (hereinafter referred to as Omega-3-Fatty Acid Ethyl Esters).

The RMP details important risks of Omega-3-Fatty Acid Ethyl Esters, how these risks can be minimised, and how more information will be obtained about Omega-3-Fatty Acid Ethyl Esters's risks and uncertainties (missing information).

Omega-3-Fatty Acid Ethyl Esters's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Omega-3-Fatty Acid Ethyl Esters should be used.

Important new concerns or changes to the current ones will be included in updates of Omega-3-Fatty Acid Ethyl Esters's RMP.

I. The medicine and what it is used for

Omega-3-Fatty Acid Ethyl Esters is indicated in Hypertriglyceridemia:

Reduction of elevated triglyceride levels when the response to diets and other non-pharmacological measures alone has proved insufficient (treatment should always be associated with an adequate dietary regimen). (See SmPC for full Indication). It contains Omega-3-Fatty Acid Ethyl Esters as an active substance and it is given orally.

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

Important risks of Omega-3-Fatty Acid Ethyl Esters together with measures to minimise such risks and the proposed studies for learning more about Omega-3-Fatty Acid Ethyl Esters'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 amount of medicine in a pack is chosen 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 the adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

In the case of Omega-3-Fatty Acid Ethyl Esters, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below

II.A List of important risks and missing information

Important risks of Omega-3-Fatty Acid Ethyl Esters 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 Omega-3-Fatty Acid Ethyl Esters. 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	Atrial Fibrillation
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: Atrial Fibrillation	
Risk Minimization measures	<p><u>Routine risk communication:</u> Listed in SmPC sections 4.4 Special warnings and precautions for use and 4.8 Undesirable effects. Listed in PIL section 2. Warnings and precautions and 4. Possible side effects</p> <p><u>Additional risk minimisation measures:</u> ➤ Direct Health care Professional Communication (DHPC)</p>
Additional pharmacovigilance activities	<p><u>Additional pharmacovigilance activities:</u> None</p>

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 Omega-3-Fatty Acid Ethyl Esters.

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

There are no studies required for Omega-3-Fatty Acid Ethyl Esters.