

EMA concludes omega-3 fatty acids medicines no longer considered effective in preventing heart disease

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Information on omega-3 fatty acid medicines

- Omega-3 fatty acid medicines contain the fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) commonly found in fish oils.
- Omega-3 fatty acid medicines have been authorised for use after a heart attack, in combination with other medicines, in several EU countries since 2000, at a dose of 1 g per day.
- At the time of omega-3 fatty acid medicines' authorisation, available data showed some benefits in reducing serious problems with the heart and blood vessels, although the benefits were considered modest. Further data that have become available since then have not confirmed the beneficial effects of these medicines for this use.

In Malta, the following product is authorised through national procedures:

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number	MAH/license holder
Omega-3-acid Ethyl Esters 90	Omacor	Soft capsule	POM	MA517/00101	Pronova BioPharma Norge AS

Information from the EMA's review conclusion on omega-3 fatty acid medicines

The review of omega-3 fatty acid medicines was started on 22 March 2018 at the request of the Swedish medicines agency under Article 31 of Directive 2001/83/EC. EMA has concluded based on the available data submitted during the review that omega-3 fatty acid medicines are not effective in preventing further heart and blood vessels problems in patients who have had a heart attack.

- The conclusion, based on a review of data accumulated over the years, means that omega-3 fatty acid medicines will no longer be authorised for preventing further heart and blood vessels problems in patients who have had a heart attack
- Although there are no new safety concerns, the Committee for Medicinal Products for Human Use (CHMP) concluded that the risk-benefit balance of omega-3 fatty acid medicines in preventing recurrence of heart disease or stroke is now negative
- Omega-3 fatty acid medicines can still be used to reduce levels of triglycerides.

The review has been carried out by the CHMP. The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

In Malta

For Healthcare Professionals

- Omega-3 fatty acid medicines will no longer be authorised for secondary prevention after myocardial infarction, based on a review of all the available data on the efficacy in this indication
- The review looked at results of the open-label ‘GISSI Prevenzione’ study performed in 1999 which supported the initial authorisation of omega-3 fatty acid medicines, as well as retrospective cohort studies, randomised controlled trials and results of meta-analyses
- The review concluded that, while a small relative risk reduction was seen in the original open label ‘GISSI Prevenzione’ study, such beneficial effects were not confirmed in more recent randomised controlled trials
- This review does not affect the authorisation of omega-3 fatty acid medicines for the treatment of hypertriglyceridaemia.

Advice for Patients

- Latest data on omega-3 fatty acid medicines show that these medicines are not effective at preventing further problems with the heart and blood vessels in patients who have had a heart attack
- There are alternative treatment options to prevent recurrence of heart problems after a heart attack
- If you are using omega-3 fatty acid medicines to reduce the risk of heart problems your doctor will advise on the best alternative treatment option for you
- Omega-3 fatty acid medicines are still authorised to reduce levels of certain types of blood fat called triglycerides. Therefore, if you are using these medicines for this purpose you should continue your treatment
- There are no new safety concerns associated with the use of omega-3 medicines
- If you have any questions or concern about omega-3 fatty acid medicines, contact your treating doctor

For more information visit the European Medicines Agency’s [Omega-3-fatty-acid-medicines referral page](#)

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Omega-3 fatty acid medicines. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form (available from: <http://www.medicinesauthority.gov.mt/adrportal>) and sent by mail to Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or email to postlicensing.medicinesauthority@gov.mt or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate

Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

Post-Licensing Directorate

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