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EMA confirms omega-3 fatty acid medicines are not effective in preventing further heart problems after a heart attack

On 29 March 2019 EMA confirmed that omega-3 fatty acid medicines containing a combination of an ethyl ester of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) at a dose of 1 g per day are not effective in preventing further problems with the heart and blood vessels in patients who have had a heart attack. This is the outcome of a re-examination requested by some of the companies that market the medicines concerned, following EMA's original recommendation in December 2018.

This means that these medicines should no longer be used in this way. However, they can still be used to reduce levels of certain types of blood fat called triglycerides.

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 their authorisation, available data showed some benefits in reducing serious problems with the heart and blood vessels.

EMA's committee for human medicines, CHMP, re-assessed the evidence accumulated over the years on these medicines for this specific use and consulted additional experts in the field. It concluded that, although there are no new safety concerns, the effectiveness of these medicines in preventing recurrence of problems with the heart and blood vessels has not been confirmed.

EMA concluded that the marketing authorisations of these medicines should be updated to remove this use.

Information for patients

- A review of all available data on omega-3 fatty acid medicines containing a combination of an ethyl ester of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) shows that these medicines are not effective at preventing further problems with the heart and blood vessels in patients who have had 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- Omega-3 fatty acid medicines are still authorised for reducing 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 question or concern about omega-3 fatty acid medicines contact your treating doctor.

Information for healthcare professionals

- Omega-3 fatty acid medicines containing a combination of an ethyl ester of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) will no longer be authorised for secondary prevention after myocardial infarction.
- This is based on a review of all the available data on the efficacy of omega-3 fatty acid medicines in this indication.
- The review looked at results of the open-label 'GISSI Prevenzione' study performed in 1999 which supported the initial authorisation of these medicines, as well as more recent randomised controlled clinical trials, retrospective cohort studies and meta-analyses.
- The review concluded that, while a small relative risk reduction was seen in the original open label GISSI Prevenzione study, the 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.

More about the medicines

The review concerned omega-3 fatty acid medicines containing a combination of an ethyl ester of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). EPA and DHA are commonly found in fish oils.

Omega-3 fatty acid medicines are taken by mouth and have been authorised in several EU countries through national procedures. This review focused on the medicines' use in patients who have had a heart attack.

More about the procedure

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.

The review was carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which adopted an opinion in December 2018.

Following a request from some marketing authorisation holders, the CHMP re-examined its original opinion and adopted its final opinion, which was forwarded to the European Commission. The European Commission issued a final legally binding decision applicable in all EU Member States on 6 June 2019.