EMA/19056/2019 Rev.1

Update of 1 February 2019:

Following the CHMP's recommendation of 13 December 2018, some of the marketing authorisation holders involved with this review have requested a re-examination. Upon receipt of the grounds for their requests, the CHMP will start a re-examination, which is expected to conclude at the CHMP meeting of 25-29 March 2019.

14 December 2018

Omega-3 fatty acid medicines no longer considered effective in preventing heart disease

EMA has concluded 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 these medicines will no longer be authorised for such use.

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, 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.

Although there are no new safety concerns, EMA's human medicines committee (CHMP) concluded that the balance between the benefits and risks of these medicines to prevent recurrence of heart disease or stroke is now negative.

These medicines can still be used to reduce levels of certain types of blood fat called triglycerides.

Information 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- 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.

Information for healthcare professionals

- Omega-3 fatty acid medicines 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 retrospective cohort studies, more recent 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.

More about the medicine

Omega 3-fatty acid medicines contain the fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) commonly found in fish oils. They are taken by mouth and are authorised in several EU countries for preventing heart disease or stroke after a heart attack (in combination with other medicines) and for reducing certain types of blood fats. This review is 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 has been carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has adopted the Agency's opinion. 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.