

# Omega-3 fatty acid medicines for schizophrenia

Information for the public

Published: 24 September 2013

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## About this information

This information explains the evidence summary about the off-label use of omega-3 fatty acid medicines for treating schizophrenia. The evidence summary is an overview of the available information about this medicine. It aims to help prescribers and patients when they are considering whether or not to use an unlicensed or off-label treatment. The summary does not contain recommendations from NICE on whether the medicine should be used.

## Licensing medicines

In the UK, medicines need to have a licence before they can be marketed. To get a licence, the manufacturer of the medicine has to provide evidence that shows that the medicine works well enough and is safe enough to be used for a specific condition and for a specific group of patients, and that they can manufacture the medicine to the required quality. Medicines can be prescribed without a licence (an 'unlicensed medicine') if there is no suitable licensed alternative and it is likely to benefit the patient.

A medicine can also be prescribed 'off-label'. This means the prescriber wants to use it in a different way than is set out in the terms of its licence. This could mean using the medicine for a different condition or a different group of patients, or it could mean a change in the dose or that the medicine is taken in a different way. There is more information about licensing medicines on [NHS Choices](#).

## What is schizophrenia?

Schizophrenia is a serious mental health condition that affects a person's mental state, including their thoughts, mood and behaviour. The condition varies from person to person but the main symptoms are called 'psychotic' symptoms. These are:

- hearing voices and sometimes seeing things that are not really there (called hallucinations)
- having fixed beliefs that are false but which the person believes in completely (called delusions).

Because of these symptoms the person may not be able to think clearly or concentrate. They may lose interest in things, lack motivation and become withdrawn from other people.

Schizophrenia affects about 1 in every 100 people. It is usually treated with a type of medication called 'antipsychotic' medication and psychological therapy (a treatment that involves meeting with a healthcare professional to talk about feelings and thoughts and how these affect behaviour and wellbeing).

## About omega-3 fatty acids

Omega-3 fatty acids are a type of fat necessary for human health. They are known as essential fatty acids because the body can't make them on its own, so it must get them from food and drink. People can get them through a variety of different foods such as oily fish (like salmon, sardines or fresh tuna), certain vegetables and cereals. Omega-3 fatty acids can also be purified into a liquid or capsule.

Omega-3 fatty acid capsules and liquids are available as either approved medicines or as food supplements. The omega-3 fatty acid capsules and liquids that have been approved as medicines have had to meet certain requirements to help make sure that they are of a

certain level of quality and that they are safe. However, those that are food supplements have not, which means there are fewer quality checks carried out on the product.

Some omega-3 fatty acid medicines are licensed, in combination with other medicines, for people who have had a heart attack to help to prevent them from having another one. Others are used to help lower higher-than-normal levels of fats and cholesterol in the blood, after changes to the diet have not worked. However, whether omega-3 fatty acid supplementation has a beneficial effect on the prevention of cardiovascular disease is debated.

Omega-3 fatty acid medicines are not licensed in the UK to treat schizophrenia, so their use in this way is described as off-label.

Purified omega-3 fatty acids have been tested in a research setting to see if they improve symptoms of schizophrenia. They have been given to people with schizophrenia in addition to using antipsychotic medications and psychological therapies (see [What is schizophrenia?](#) for more information). They are not intended to replace these existing treatments.

## Summary of possible benefits and harms

### How well do omega-3 fatty acid medicines work?

Eight studies looked at how well omega-3 fatty acids worked to improve symptoms of schizophrenia. The studies did not include many people and did not last longer than 3 to 4 months. This means their results are not very reliable and don't tell us anything about any longer term effects.

The studies all looked at how well omega-3 fatty acid medicines worked compared with a dummy pill containing no active ingredient (also known as a placebo).

The results were mixed. Four out of the 8 studies showed that omega-3 fatty acids were slightly better than the dummy pills, leading to small improvements in some ratings scores that measure schizophrenia symptoms. However, the other 4 studies showed that omega-3 fatty acids were no better than the dummy pills at improving symptoms. This evidence therefore suggests omega-3 fatty acid medicines either don't work or may have small effects but, as mentioned, the evidence is not very reliable.

## What are the possible harms or side effects?

As with all medicines, there are some possible side effects, although not everyone gets them.

Omega-3 fatty acid medicines may increase the time it takes a person's blood to clot, which can be important in people with existing blood clotting problems or in situations where bleeding for longer than normal may be a problem, such as during surgery.

The most common side effects of using omega-3 fatty acid medicines are stomach problems and indigestion, and feeling sick. These occur in between 1 and 10 in every 100 people taking the medicine.

Results from the studies did not find any serious harm linked to omega-3 fatty acids when used for up to 4 months in people with schizophrenia. However, the possible harms or side effects of taking omega-3 fatty acids for longer than this in people with schizophrenia were not studied and so are not known.

Please note that the results of the research studies only indicate the benefits and harms for the population in those studies. It is not possible to predict what the benefits and harms will be for an individual patient being treated with omega-3 fatty acid medicines.

## Prescribing omega-3 fatty acid medicines

If a prescriber wants to use an unlicensed or off-label medicine, they must follow their professional guide, for example for doctors the General Medical Council's [good practice guidelines](#). These include giving information about the treatment and discussing the possible benefits and harms so that the patient has enough information to decide whether or not to have the treatment. This is called giving informed consent.

A [full version of the summary aimed at healthcare professionals](#) is available on the NICE website. The summary for healthcare professionals does not contain recommendations from NICE on whether the medicine should be used.

## Questions to ask

- Why am I being offered an off-label medicine?
- Could I take a food supplement instead?
- What does the treatment involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits?
- Could having the treatment make me feel worse?
- Are there alternative treatments?
- What are the risks of the treatment?
- Are the risks minor or serious? How likely are they to happen?
- What may happen if I don't have the treatment?

## More information

The evidence summary and this information for the public were produced for NICE by Bazian Ltd.

NICE has published [information](#) about how evidence summaries for unlicensed and off-label medicines are developed.

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### Contact NICE

National Institute for Health and Care Excellence  
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

