



Fluoxetine for hypersexuality

Information for the public Published: 21 July 2015

www.nice.org.uk

About this information

This information explains the evidence summary about the off-label use of fluoxetine for hypersexuality (increased sex drive). 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 it 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 hypersexuality?

People with hypersexuality have an unusual or excessive interest in sex.

Treatments for hypersexuality in men include medicines that reduce the amount of testosterone (the male sex hormone) that the body produces. These include a medicine called cyproterone acetate and another medicine called triptorelin.

Fluoxetine (or other medicines similar to it) may be used to treat hypersexuality. However, fluoxetine is not licensed for treating hypersexuality so its use for this indication is off-label.

About fluoxetine

Fluoxetine is an antidepressant. In adults it is usually used to treat depression or obsessive compulsive disorders (OCD). Fluoxetine can also reduce people's sex drive so it is sometimes used to treat hypersexuality.

Summary of possible benefits and harms

How well does fluoxetine work?

Three small studies have looked at how well fluoxetine works to treat hypersexuality. One study was in men who were in prison for committing a sexual offence. The other 2 studies were in men who had unusually frequent or abnormal sexual fantasies, urges and sexual behaviours. These studies found that fluoxetine reduced the number of times men with hypersexuality took part in sexual activities. It also reduced the number of thoughts and fantasies the men had about sex.

However, these studies were all small and had several problems with their design.

Therefore, they do not provide good information about how well fluoxetine works to treat hypersexuality. The studies did not look at treating hypersexuality in women.

What are the possible harms or side effects?

Some people may get side effects when taking fluoxetine. The following ones have been reported to occur in 1 in 10 people or more:

- · feeling tired
- feeling or being sick
- diarrhoea
- headache
- · problems sleeping.

Please note that the results of research studies only indicate the benefits and harms for the population in the studies. It is not possible to predict what the benefits and harms will be for an individual person being treated with fluoxetine.

Prescribing fluoxetine

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 person has enough information to decide whether or not to have the treatment. This is called giving informed consent.

A <u>full version of the summary aimed at healthcare professionals</u> 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?

- 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

NICE has published <u>information</u> about how evidence summaries for unlicensed and off-label medicines are developed.

Copyright

© National Institute for Health and Care Excellence, 2015. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

ISBN: 978-1-4731-1300-8