

Chronic urticaria: higher (off-label) doses of cetirizine

Information for the public

Published: 8 July 2014

www.nice.org.uk

About this information

This information explains the evidence summary about the off-label use of higher doses of cetirizine for chronic urticaria (a raised, itchy rash that lasts for a long time or keeps recurring). 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 chronic urticaria?

Urticaria is a raised, itchy skin rash. When the rash lasts for more than 6 weeks or when it keeps coming back, it is known as chronic urticaria. Chronic urticaria can last for months or years. Often the cause is not known, but it may be triggered by a virus, stress or medicines.

If possible, the cause of urticaria should be identified and managed. People who need treatment are usually offered an antihistamine. This should be one that doesn't cause drowsiness at the standard dose. In some people, symptoms don't improve with this treatment. When this happens it is common practice to increase the dose of antihistamine if the benefits are likely to outweigh the risks.

About cetirizine

Cetirizine is an antihistamine that doesn't usually cause drowsiness when used at the standard dose. It is licensed for treating chronic urticaria at a dose of 10 mg daily in adults and young people aged over 12 years, 5 mg twice daily in children aged 6–12 years, and 2.5 mg twice daily in children aged 2–6 years. Use of higher doses of cetirizine is off-label.

Summary of possible benefits and harms

How well does cetirizine work?

Four small studies have looked at how well cetirizine 20 mg (double the standard dose) works for treating chronic urticaria when symptoms haven't improved with standard doses of antihistamines. Most people in the studies were aged 16–65 years. No studies included children and young people under 16 and there were very few older adults (over 65 years). No studies looked at cetirizine 40 mg, a dose that is sometimes used for treating chronic

urticaria.

Overall, the studies suggest that cetirizine 20 mg improves rash and itching in adults compared with placebo (a dummy tablet) or a standard 10 mg dose of cetirizine. However, not everyone had improvements in their symptoms. Also, because of the small size and the design of the studies, they do not provide good evidence about the benefits and harms of cetirizine.

What are the possible harms or side effects?

Standard doses of cetirizine (10 mg) can cause tiredness, dizziness, headache, abdominal pain, dry mouth, nausea, drowsiness and sore throat. However, few adverse effects were reported in the small studies and cetirizine seemed to be well tolerated.

Please note that the results of the 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 patient being treated with higher (off-label) doses of cetirizine.

Prescribing cetirizine

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

Copyright

© National Institute for Health and Care Excellence, 2014. 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 978-1-4731-0642-0