Glycopyrronium for excessive sweating

Information for the public Published: 9 July 2013

www.nice.org.uk

About this information

This information explains the evidence summary about the unlicensed use of glycopyrronium for treating excessive sweating. 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 excessive sweating?

Excessive sweating (also called hyperhidrosis) is when a person sweats more than is necessary to cool their body down and maintain normal body temperature. When it isn't known what has caused the excessive sweating, this is called 'primary hyperhidrosis'. This mostly affects only specific areas of the body, such as the palms of the hands and the soles of the feet, the underarms, or the face and scalp. Primary hyperhidrosis affects both men and women, and most commonly starts before the age of 18.

When it is known what has caused the excessive sweating, this is called 'secondary' hyperhidrosis'. Examples of conditions that can cause secondary hyperhidrosis are an overactive thyroid, or going through the menopause. Secondary hyperhidrosis most commonly affects the whole body, rather than specific areas.

Sometimes people have surgery as a last resort to control excessive sweating of the palms, soles or underarms. During the surgery, the nerves that cause the sweating are cut which stops the sweating. However, after surgery, sweating can sometimes develop in another part of the body that was not affected before. When this happens this is called 'compensatory' sweating or 'compensatory hyperhidrosis'.

About glycopyrronium

Glycopyrronium (also called glycopyrronium bromide) is a medicine that aims to stop the stimulation of sweat glands and reduce sweating.

Glycopyrronium is only licensed for treating excessive sweating if used in an electrical treatment called 'iontophoresis' for the palms of the hands and soles of the feet. During this treatment, the hands or feet are placed in plastic trays containing a liquid that has glycopyrronium in it, and a very small electrical current is passed through the liquid.

When glycopyrronium is taken by the mouth (orally) as tablets or as a liquid for treating

of 5

excessive sweating, this use is unlicensed in the UK. This evidence summary has looked at how well glycopyrronium works and how safe it is when it is taken by the mouth for treating excessive sweating.

There are other ways to reduce sweating. Simple options include using antiperspirants containing aluminium chloride, and wearing clothes that keep you cool. Besides iontophoresis, Botox is another treatment that is licensed specifically for treating severe sweating of the underarms.

Summary of possible benefits and harms

How well does glycopyrronium work?

No studies have looked at how well glycopyrronium tablets or liquid work for reducing excessive sweating when compared with other treatments.

The only information available comes from reports of the experiences of individual people who have been treated with glycopyrronium tablets at different medical centres. Five of these reports have been published: 3 reports included 100 adults with excessive sweating of unknown cause; 1 report included 31 children or young people with excessive sweating of unknown cause; and 1 report included 19 people with a type of sweating called 'compensatory hyperhidrosis'.

Across these 5 reports, glycopyrronium tablets improved sweating to some degree for between 7 and 9 people out of every 10 who took this medicine, but it is difficult to know how well it worked for each person. The remaining people who took glycopyrronium either did not find that it improved their sweating, or they experienced side effects that caused them to stop taking the medicine.

These 5 reports provide only weak evidence on whether glycopyrronium tablets work well for treating excessive sweating.

What are the possible harms or side effects?

Across the 5 reports side effects of glycopyrronium were common, affecting between 3 and 8 out of every 10 people who took this medicine. The most common side effect was a

dry mouth. Other side effects experienced less often were dry eyes, headache, an unsettled stomach, and feeling that their heart was racing (called palpitations). In 2 of the 5 reports, around a quarter of adults taking glycopyrronium stopped taking the medicine because of side effects. In the report in young people, 1 young person stopped taking glycopyrronium because of palpitations. In the other 2 reports, no one stopped taking the medicine because of side effects.

In the USA, glycopyrronium tablets and liquid are available, but these are not licensed for treating excessive sweating. The US tablets are not recommended if the person has certain medical conditions such as:

- glaucoma (a condition where pressure builds up in the eye which can affect vision)
- severe ulcerative colitis (a condition where the lower part of the gut becomes inflamed which can cause pain and bloody diarrhoea)
- myasthenia gravis (a condition causing muscle weakness, particularly in the upper part of the body such as the eyelids, face, neck and arms).

There are also warnings of some stomach problems that can happen, and it is suggested that a person avoids very hot temperatures because it can reduce how much a person sweats.

Please note that the results of the reports only indicate the benefits and harms for the people in these reports. It is not possible to predict what the benefits and harms will be for an individual patient being treated with glycopyrronium.

Prescribing glycopyrronium

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 <u>good practice</u> <u>guidelines</u>. 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 <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 unlicensed 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

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 offlabel medicines are developed.

Copyright

© Bazian Ltd, 2013. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. If you wish to reproduce this information for use by commercial organisations or for commercial purposes, please email NICE.

Contact NICE

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

www.nice.org.uk; nice@nice.org.uk; 0845 003 7780