Glycopyrronium for increased saliva production or drooling

Information for the public
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About this information

This information explains the evidence summary about the unlicensed use of glycopyrronium for treating increased saliva production or drooling. 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 increased saliva production?

Increased saliva production (sometimes called hypersalivation) is when a large amount of saliva is produced in the mouth. It is one of the causes of drooling, which may become a problem for a person if there is too much saliva to control or a person has difficulty swallowing. Drooling is normal in babies. If a large amount of drooling continues past the age of 4 years it may be caused by increased saliva production or difficulties in swallowing saliva. Problem drooling can cause embarrassment, discomfort, chapped lips, irritation and softening or infection of the skin.

Increased saliva production or drooling can sometimes happen in conditions that affect a person’s brain such as cerebral palsy or Parkinson's disease. It can also happen as a side effect of taking some medicines.

If drooling becomes a problem for the person or there is a high amount of saliva that cannot be controlled, there are some medicines which can be tried.

About glycopyrronium

Glycopyrronium (also called glycopyrronium bromide) is a medicine that aims to reduce saliva production. It can be taken by the mouth (orally) as tablets or as a liquid for treating increased saliva production or drooling in children, young people or adults, but this use is unlicensed in the UK.

Glycopyrronium can be taken in different ways. It is licensed when it is breathed in (inhaled) for treating a lung disease called chronic obstructive pulmonary disease in adults. It is also licensed in children and adults as an injection for use before or during an operation, and for treating excessive sweating if used in an electrical treatment called ‘iontophoresis’.

This evidence summary has only looked at how well glycopyrronium works and how safe it is when it is taken by the mouth for treating increased saliva production or drooling.

Glycopyrronium is 1 type of treatment that may be used to try and reduce the amount of saliva a person produces. The main aim of treatment is to lower the amount of saliva that is produced so that drooling is reduced. Other medicines have been used for treating increased saliva production (or hypersalivation), but none are licensed in the UK for this use.
Summary of possible benefits and harms

How well does glycopyrronium work?

There are very few studies that have looked at how well glycopyrronium works for treating increased saliva production or drooling.

Two studies, including a total of 77 children and young people, compared glycopyrronium capsules or liquid with a dummy treatment for 8 weeks. The children and young people were aged between 3 and 19 years and all had a condition affecting their brain, most commonly cerebral palsy. Glycopyrronium was given 3 times a day and the amount of drug was increased slowly during each study. Drooling was rated by the parent or carer of the child or young person. Both studies found glycopyrronium reduced drooling compared with the dummy treatment. In 1 of the studies, drooling went from severe to either no drooling or mild drooling in those receiving glycopyrronium. In the other study, drooling was improved in around three-quarters of children and young people given glycopyrronium and less than one-fifth of those given the dummy treatment.

One study of 23 adults with Parkinson's disease compared glycopyrronium liquid with a dummy treatment for 1 week. The adults had an average age of 70. Glycopyrronium reduced drooling more than the dummy treatment, and drooling improved from severe to mild or moderate in these people.

One other study was of 13 adults with schizophrenia who had increased saliva production that was caused by a medicine they were taking. Glycopyrronium was compared with another unlicensed medicine (called biperiden) for 4 weeks to see if it reduced saliva production. Both medicines were found to reduce the amount of saliva produced after 4 weeks, and glycopyrronium was found to work better than biperiden. Drooling improved from severe to mild or moderate for people who were given glycopyrronium.

What are the possible harms or side effects?

Glycopyrronium can be associated with unpleasant side effects. Most commonly it can cause dry mouth, vomiting (throwing up), constipation (being unable to pass stools), flushing (reddening of the face or body) and nasal congestion (stuffy nose).

In the USA, liquid glycopyrronium has been approved for treating chronic severe drooling in children and young people aged 3 to 16 years who have a brain condition. This medicine is 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. It is also suggested that a person avoids very hot temperatures because as well as reducing the amount of saliva, it can also reduce how much a person sweats.

In the 2 studies of children and young people, a lot more of the children or young people who were given glycopyrronium said they experienced side effects compared with those who received the dummy treatment. In total, there were 8 people who stopped treatment while taking glycopyrronium compared with 2 people who stopped while taking the dummy treatment.

In the study of adults with Parkinson's disease, there was no difference in the side effects that people taking glycopyrronium or the dummy treatment experienced, but people only took the treatment for 1 week.

In the study of people with schizophrenia who had increased saliva production because of medicines they were taking, it is not clear how many people had side effects. It is reported that the amount of side effects was similar for people receiving glycopyrronium and people receiving the other medicine (biperiden). However, the people who took biperiden scored worse on a test of arithmetic, memory and awareness of time and place (cognition); the people who took glycopyrronium did not have a worsening in their cognition.

As the studies were all for a short period of time, what happens when people take glycopyrronium for long periods is not known. Studies for longer periods of time are needed to be able to find this out.

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 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 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 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 off-label medicines are developed.

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