

Fludrocortisone for low blood pressure on standing (postural hypotension)

Information for the public

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About this information

This information explains the evidence summary about the off-label use of fludrocortisone for low blood pressure on standing. This is known as postural hypotension or orthostatic hypotension. 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 postural hypotension?

Postural hypotension (also called orthostatic hypotension) is a condition in which a person's blood pressure drops abnormally when they stand up after sitting or lying down. Not all people who have this condition have symptoms, but it can lead to dizziness, light-headedness and fainting, and possible falls.

Postural hypotension is more common in older people, and in people who have conditions such as Parkinson's disease or diabetes, which affect the part of the nervous system that helps to control blood pressure. People can also get the condition if they are dehydrated, or are taking certain medicines (for example, to treat high blood pressure).

About fludrocortisone

Fludrocortisone is a type of drug called an oral mineralocorticoid, often shortened to 'steroids'. The drug is licensed for treating a condition called Addison's disease, in which glands attached to the kidneys (called adrenal glands) do not make enough of certain hormones. Fludrocortisone helps to replace these hormones. It is also licensed to treat a condition called 'salt losing adrenogenital syndrome', another form of hormone imbalance. Fludrocortisone is also used to raise blood pressure in people with postural hypotension, but it does not have a UK licence for this, and so its use to treat postural hypotension is called 'off-label'. It raises blood pressure by increasing sodium (salt) levels and affecting blood volume.

There are other treatments that can be tried for postural hypotension which do not involve taking drugs. These include drinking more water, using compression garments, raising the head of the bed, and learning body movements to counteract the drop in blood pressure.

Some other drugs, with UK licences for use in other conditions, are prescribed 'off-label' to treat postural hypotension (these include domperidone and pyridostigmine). Midodrine is another drug that is used to treat postural hypotension, but it does not have a licence for any use in the UK, so use for any condition, including postural hypotension, is 'unlicensed'. Midodrine is licensed for use in postural hypotension in some other countries. NICE has published an evidence summary on the

unlicensed use of [midodrine for treating postural hypotension in adults](#).

Summary of possible benefits and harms

How well does fludrocortisone work?

There has been limited research into the use of fludrocortisone for treating postural hypotension.

One very small study compared fludrocortisone with a 'dummy' tablet (known as placebo) in 6 people with postural hypotension caused by diabetes. This found that fludrocortisone taken for 3 weeks improved postural hypotension more than the 'dummy' tablet.

Another small study compared fludrocortisone with non-drug treatments in 17 people with postural hypotension and Parkinson's disease. This found that 3 weeks treatment with fludrocortisone slightly improved symptoms of postural hypotension.

Another slightly larger study compared fludrocortisone with a 'dummy' tablet in 100 people with chronic fatigue syndrome (feeling very tired and generally unwell). This study found that fludrocortisone taken for 9 weeks did not improve wellness compared with the 'dummy' tablet.

These studies provide very limited evidence that fludrocortisone may improve postural hypotension. However, because none of the studies lasted for more than 9 weeks and they did not include many people, the results are not conclusive.

What are the possible harms or side effects?

The manufacturers of fludrocortisone recommend that it is not suitable for people with certain serious bacterial or viral infections unless they receive particular treatment for the infection. They also recommend that blood pressure, swelling, weight gain, salt levels and side effects associated with corticosteroids (similar drugs to fludrocortisone) should be monitored in people receiving fludrocortisone. Oral steroids including fludrocortisone may weaken the immune system, which could increase the risk of getting a serious infection. There is a warning that people taking fludrocortisone who haven't had chicken pox should keep away from anyone with chicken pox. Exposure to measles and shingles should also be avoided. People should seek medical advice if they are exposed to chicken pox, shingles or measles while taking fludrocortisone.

Oral steroids including fludrocortisone can cause serious mental health problems. They can affect about 5 in every 100 people taking medicines like fludrocortisone.

If oral steroids like fludrocortisone have been taken for more than 3 weeks, the dose should be gradually reduced when it is stopped unless a healthcare professional advises otherwise. People taking fludrocortisone should carry a steroid treatment card. This card should always be carried with them and shown to anyone who treats them (for example, a doctor, nurse, pharmacist or dentist).

About a quarter of those (13 out of 50) taking fludrocortisone in the 9-week study stopped taking the drug. Reasons included: depression (4 people), abdominal (stomach) discomfort (2 people), worsening symptoms (2 people), high blood pressure (1 person), and worsening headaches (1 person). Out of 50 people taking the 'dummy' tablet, 8 stopped taking it. At least 1 side effect was reported by around 30 in every 50 people taking fludrocortisone compared with around 35 in every 50 people taking the 'dummy' tablet.

In the study in 6 people with postural hypotension caused by diabetes, 2 people developed ankle swelling while taking fludrocortisone. This quickly got better when fludrocortisone was stopped.

The 3 studies of the use of fludrocortisone for postural hypotension lasted for no longer than 9 weeks, so they don't tell us how well fludrocortisone works or how safe it is if taken for longer than this. Another study did look at the possible harms or side effects of fludrocortisone in older people taking it for about 1 year. This study only looked at the possible harms or side effects of the drug and not at how well the drug works. It had several limitations including that it did not have a comparison group, but found that 38 of 64 people (59%) had side effects with 17 people stopping taking the drug due to these side effects. Reasons for stopping taking the drug were: heart failure (7 people), high blood pressure (4 people), depression (3 people), thought by the patient to be of no benefit (2 people) and stroke (1 person).

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 fludrocortisone.

Prescribing fludrocortisone

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

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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