



Flunarizine for preventing migraines

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About this information

This information explains the evidence summary about the unlicensed use of flunarizine for preventing migraines. 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 migraine?

Migraine is a type of headache. Headaches are a very common health problem. Most headaches, including migraines, are called 'primary headaches', which means that they do not have an underlying cause. Symptoms of migraine include a pulsating, throbbing or banging pain in your head, there may be an unusual sensitivity to bright lights or loud sounds, and you may feel sick or vomit (be sick). The length of time a migraine lasts can vary between 1 hour and 3 days. Some people with migraines have symptoms called 'auras'. These auras can happen on their own (without a migraine headache) or together with a migraine headache. Common symptoms of an aura are: problems with sight such as seeing flickering lights, spots or lines, or a loss of vision, pins and needles or numbness, or problems speaking. Auras are temporary. They take at least 5 minutes to develop, and last for between 5 minutes and 1 hour.

Depending on how often a person has migraines and what impact they have on the person's life, medication may be used to try and reduce the number of migraines that a person has. Medicines that may be used to prevent migraines include propranolol and topiramate. Other medicines are used if these are not suitable or don't work.

About flunarizine

Flunarizine is a type of drug known as a calcium channel blocker. Calcium channel blockers are medicines that are most often used to reduce blood pressure or treat certain heart conditions. Flunarizine is not licensed in the UK, and so its use for preventing migraine is 'unlicensed'.

To try and prevent migraine in adults, flunarizine 5 mg or 10 mg is usually taken once a day (at night). After flunarizine has been taken for a while, it may be recommended that people have 2 successive 'tablet-free' days each week, such as Saturday and Sunday. After 6 months of taking flunarizine a complete break from taking it is often recommended. It may be restarted if the migraines get worse again during this 6 month period.

Summary of possible benefits and harms

How well does flunarizine work?

Four studies looked at how well flunarizine worked in adults at reducing the number of migraines they had. None of the studies took place in the UK.

Three of the studies compared flunarizine with a drug called propranolol, and 1 compared flunarizine with a drug called topiramate. Overall the studies suggest that, in adults, flunarizine works as well as propranolol and topiramate at reducing the number of migraines people have.

Six small studies looked at flunarizine for preventing migraine in children and young people. Two of these studies compared flunarizine with a 'dummy tablet' (which is a tablet that doesn't contain any medicine – this is also known as a placebo), and 4 studies compared it with other medicines for preventing migraines. Overall the studies suggest that flunarizine reduces the number of migraines children and young people have compared with the 'dummy tablet' and that it works as well as the other treatments it was compared with. However, because of the small size and the design of the studies they do not provide good evidence on how well flunarizine works in children and young people.

What are the possible harms or side effects?

Flunarizine should not be taken by people with depression or by people with Parkinson's disease or movement disorders. Weight gain is a very common side effect with flunarizine, which can affect about 10 in every 100 people taking it. Other possible side effects include a blocked or runny nose, increased appetite, depression, not being able to sleep or sleeping too much, constipation, stomach discomfort, feeling sick, muscle pain, menstruation problems, breast pain or tiredness. These side effects can affect between about 1 to 10 of every 100 people taking flunarizine.

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 flunarizine.

Prescribing flunarizine

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 <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

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

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