

# Ondansetron for vomiting in children and young people with gastroenteritis

Information for the public  
Published: 7 October 2014

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## About this information

This information explains the evidence summary about the off-label use of ondansetron for treating nausea (feeling sick) and vomiting (being sick) in children and young people with gastroenteritis. The evidence summary is an overview of the available information about this medicine. It aims to help prescribers and patients (and their parents or carers if appropriate) 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 gastroenteritis?

Gastroenteritis is a type of infection in the gut. Children and young people with gastroenteritis usually have loose or watery stools (diarrhoea) and may also be sick (vomit). Most children and young people with gastroenteritis get better quickly without treatment and can be looked after at home safely. However, severe diarrhoea and vomiting can lead to dehydration, which is when the body doesn't have enough water or the right balance of salts to carry out its normal functions. Children and young people who are dehydrated often feel and look unwell, and if the dehydration becomes severe it can be dangerous. Dehydration is more likely to occur in young babies, and in children and young people who haven't been able to drink enough during their illness or whose diarrhoea and vomiting has been severe.

## About ondansetron

Ondansetron is an anti-sickness medicine. It works by stopping a chemical in the body called serotonin from making you feel sick.

Ondansetron is licensed in the UK to prevent or treat sickness caused by chemotherapy, radiotherapy or surgery in adults, and chemotherapy or surgery in children and young people. Ondansetron is not licensed to treat sickness in children and young people with gastroenteritis, therefore using it in this way is off-label.

Ondansetron can be given as a tablet (these can be tablets that need to be swallowed, or tablets that melt in the mouth called orodispersible tablets), as a liquid medicine taken by the mouth, as a suppository (for use in the back passage [rectum]), and by an injection.

# Summary of possible benefits and harms

## How well does ondansetron work?

Eight studies looked at how well ondansetron works for treating sickness in children and young people aged 3 months to 13 years with gastroenteritis. Ondansetron was given as tablet which melts in the mouth (called an orodispersible tablet), as a liquid medicine taken by the mouth, or by an injection. Most of the children and young people in the studies who took ondansetron were given just 1 dose of the medicine, with the amount given based on how much they weighed. All the studies were carried out in emergency departments of children's hospitals, but none were in the UK.

More children and young people in the studies were stopped from being sick when they had ondansetron compared with those who had a dummy treatment (which is a treatment with no medicine in it). Fewer children and young people also needed to have fluids given to them through a drip into a vein to treat severe dehydration or had to stay in hospital when they had ondansetron.

## What are the possible harms or side effects?

In the studies, more children and young people given ondansetron had diarrhoea compared with those who had the dummy treatment.

Other common side effects of ondansetron (affecting less than 1 in 10 people) can be headache, constipation and feeling flushed. Uncommon side effects (affecting less than 1 in 100 people) include hiccups, chest pain, uneven heartbeat, slow heart rate, feeling dizzy when getting up, fits, and unusual body movements. Ondansetron may not be suitable for people with heart problems or an irregular heartbeat.

Please note that the results of the research studies only indicate the benefits and harms for the population in the study. It is not possible to predict what the benefits and harms will be for an individual patient being treated with ondansetron.

# Prescribing ondansetron

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, parent or carer 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 or my child being offered an off-label medicine?
- What does the treatment involve?
- What are the benefits I or my child might get?
- How good are my or my child's chances of getting those benefits?
- Could having the treatment make me or my child 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 or my child don't have the treatment?

## More information

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

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ISBN: 978-1-4731-0800-4