

Using domperidone to improve feeding tolerance in children and young people being tube fed

Information for the public

Published: 30 July 2013

www.nice.org.uk

About this information

This information explains the evidence summary about the off-label use of domperidone to improve feeding tolerance in children and young people being tube fed. 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 feeding intolerance during tube feeding?

Tube feeding is a way of providing nutrition to people of all ages who, for a variety of reasons, cannot eat and drink normally at the time. Tube feeding typically involves a narrow tube being inserted through the nose or mouth directly into the stomach, or sometimes the gut. Sometimes, the tube is inserted directly through a hole made in the wall of the abdomen into the stomach. Once the tube is in place it can be used to deliver liquid food straight into the stomach. This means the person can get enough nutrition without eating or drinking.

Tube feeding is artificial, and bypasses the need to chew. However, chewing food helps food to be digested, and because people don't chew their food when being tube fed, food given in this way can sit in the stomach too long instead of moving into the gut to be absorbed properly. This can make people feel bloated, have stomach cramps, feel sick or be sick, regurgitate food or drink (where it comes back up into the mouth), become constipated or suffer diarrhoea. These symptoms are described as 'feeding intolerance'.

About domperidone

Domperidone is a medicine that works by helping food move faster through the oesophagus (the tube that carries food from the mouth to the stomach), stomach and gut so that the food doesn't stay in 1 place for too long. It also helps stop food travelling the wrong way back up the oesophagus.

In the UK, domperidone (available as tablets, a liquid, and as a suppository – a solid cone-shaped preparation that is inserted into the bottom) is licensed in children and young

people for the relief of symptoms of nausea and vomiting.

Currently, there aren't any treatments in the UK that are licensed to improve the symptoms of feeding intolerance in children and young people being tube fed. Using domperidone in this way is known as an 'off-label' use of the medicine. The aim of using domperidone is to help the stomach empty its contents into the gut faster and therefore relieve the symptoms of feeding intolerance

Summary of possible benefits and harms

How well does domperidone work?

Just 1 study was found that looked at how well domperidone worked in children or young people under 18 who were tube fed.

The study included 22 newborns who were born early (premature), were very underweight, and were being looked after in an intensive care unit. The newborns were tube fed (through the nose) their usual meal of milk and were also given either domperidone or water (a placebo treatment containing no active ingredient) for 48 hours.

The study found that the stomach contents of the newborns emptied faster into the gut when they were given domperidone than when they were given water and they became less constipated. However, the number of times the newborns vomited was no different when they were given domperidone than when they were given water. It wasn't clear how well the medicine improved other symptoms of feeding intolerance.

From the little evidence found, it appears that domperidone may be better than water at improving some symptoms of feeding intolerance. However, the study was very small and didn't last for long meaning the results may not be reliable. Also, because the study only included newborns, it does not provide any information on whether domperidone works in older children or young people.

Overall, there is very little evidence available to tell us how well domperidone works at improving feeding intolerance in children and young people being tube fed.

What are the possible harms or side effects?

The study in newborns was too small and short to provide reliable information on the possible harms or side effects of using domperidone.

However, domperidone has been used in studies of other conditions, and some of these studies found that domperidone may be linked to a higher risk of rare but serious heart problems, such as problems with the rhythm and electrical activity of the heart.

Because of the possibility of someone having these serious side effects while using domperidone, the medicines regulator that gives licences to drugs in Europe has started a large review of all medicines containing domperidone to determine how safe it is to use the drug. While the review is taking place, the medicines regulator says that patients should speak to their doctor or pharmacist if they have any questions or concerns.

Please note that the results of the research study 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 domperidone.

Prescribing domperidone

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 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

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.

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