The OTTER Study
Treatment Information

Your baby's OTTER treatment



You will be given one of the following treatments:

Treatment 1: Omeprazole	**Treatment 2: Placebo**
Omeprazole 2 mg/ml liquid	Omeprazole 0mg/ml liquid

The OTTER study is looking at whether a medicine called omeprazole improves the symptoms of gastro-oesophageal reflux (GOR) in babies. GOR is also known as reflux. The study is comparing omeprazole with 'placebo'. This is a liquid that looks and tastes the same as omeprazole but does not contain the medicine. Omeprazole has been used in babies for a long time and is commonly prescribed for babies with reflux symptoms, but we need more research to understand if it actually helps babies with GOR.
Your baby's OTTER treatment will be sent directly to your home by courier. You should receive the treatment within 24 hours, although there may be a slight delay if your appointment is close to a weekend or bank holiday. You will receive 2 bottles of the treatment which will be enough treatment for your baby for 4 weeks.
The amount you should give your baby (i.e. the dose), will be on the bottle label.
Please start your baby's treatment on the day you receive it.
The bottle label will have a 'do not use after' date, please **stop** your baby's treatment when this date is reached, **or the treatment has been given for 4 weeks from the date your baby started it.**

How to store your baby's medicine



When you receive your baby's treatment, **please check the bottle label and find the "reconstitution time". Your treatment should have been delivered no later than 48 hours after the reconstitution time.**

Please put the treatment in the fridge as soon as you receive it.

You will receive a text message with a link to confirm that you've received the treatment and that you were able to put in the fridge within **48 hours** of the reconstitution time. It is important you click on the link and complete this information.

What if the treatment arrives late?

If the treatment was not refrigerated within **48 hours** of the reconstitution time given on the label, it should not be given to your baby. It will not be harmful but may not be as effective. Please contact the study team as soon as possible who will arrange to have a new batch to be sent out to you.



OTTER@nottingham.ac.uk



0115 8231590

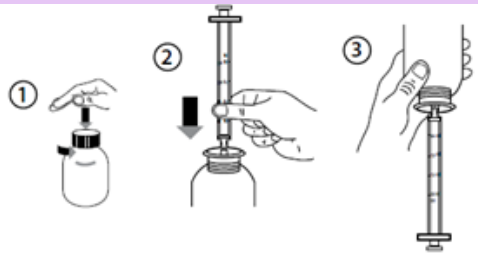
Before giving your baby the treatment

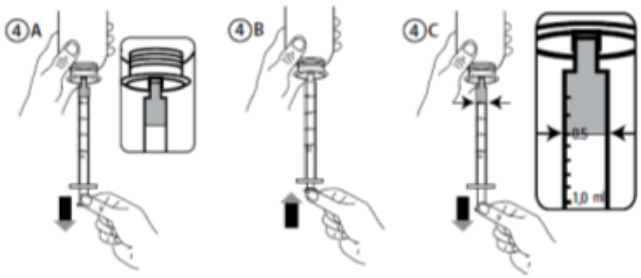
Your baby's suitability to take part in the study and be randomised to take either of the 2 study treatments will have been determined by a doctor to ensure that your baby's participation is safe. Your doctor will have checked your baby's medications before enrolling them.
Tell your doctor or pharmacist if your baby starts any new medication whilst taking the study treatment. This includes medicines that you buy without a prescription. This is because omeprazole can affect the way some medicines work and some medicines can have an effect on omeprazole.

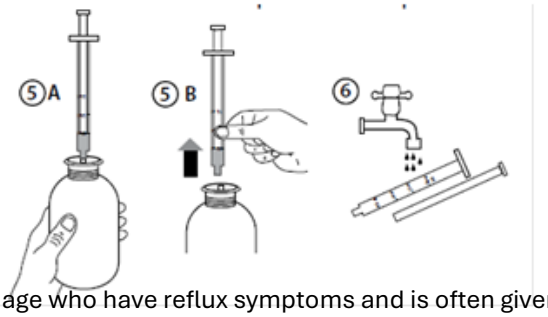
Giving the treatment

Your treatment kit will contain two bottles of treatment, two syringes to measure the dose, two bottle adaptors, and two replacement caps. You should give the treatment **once a day for 4 weeks**, **using the dose on the bottle**. You should continue to feed your baby as you wish and/or have been advised by a health professional.

Measuring your baby's dose







1. Shake the bottle for 20 seconds immediately before use
2. To open the bottle, press the grey cap down and turn it anti-clockwise (Figure 1). Do not remove the white cap.
3. Take the syringe and put it into the adaptor opening (Figure 2).
4. Turn the bottle upside down (Figure 3).
5. Fill the syringe with a small amount of treatment by pulling the plunger down (Figure 4A).Then push the plunger upward in order to remove any possible bubbles (Figure 4B). Finally, pull the plunger down to the mark showing the quantity in millilitres (ml) prescribed by your doctor. The top flat edge of the plunger should be in line with the graduation mark you are measuring to (Figure 4C).
6. Turn the bottle the right way up (Figure 5A).
7. Remove the syringe from the adaptor (Figure 5B).
8. Put the end of the syringe in your baby's mouth and push the plunger slowly to give baby the treatment. Give it in small amounts to encourage your baby to swallow it. This is easier to do if your baby is sitting up slightly rather than laying flat, and if they are calm and settled.
9. Wash the syringe with water and let it dry before you use it again (Figure 6).
10. Close the bottle with the grey plastic screw cap. Leave the bottle adaptor in the bottle.

Note: It is normal to have the red plastic disc in the treatment during use; do not attempt to remove it.

Possible side effects

Omeprazole is approved to be used for babies over one month of age who have reflux symptoms and is often given to babies younger than this. Like any medicine, omeprazole can have side effects for some individuals.
The most common side effects (affecting 1 in 10 people), include diarrhoea, stomach pain, constipation, wind (flatulence), being sick (vomiting).
Uncommon side effects (affecting 1 in 100 people) include swelling of the feet and ankles, changes in blood tests that check how the liver is working, skin rash, lumpy rash (hives) and itchy skin.
Rare side effects (affecting 1 in 1000 people) include blood problems such as a reduced number of white cells or platelets, (this can cause weakness, bruising or make infections more likely), allergic reactions (including swelling of the lips, tongue and throat, fever, wheezing), suddenly feeling wheezy or short of breath (bronchospasm), dry mouth, inflammation (redness) of the inside of the mouth, liver problems (including jaundice which can cause yellow skin, dark urine, and tiredness), hair loss (alopecia), skin rash on exposure to sunshine, joint pains (arthralgia) or muscle pains (myalgia), increased sweating.
Very rare side effects (affecting 1 in 10000 people) include sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever.

What should I do if I miss a dose or my baby spits the medicine out?

If you accidentally forget to give the medicine, give the missed dose when you remember during the day, as long as this is at least 12 hours before the next dose is due. If your child spits out the medicine or is sick less than 30 minutes after having a dose of omeprazole, give them the same dose again. However, if your child is sick more than 30 minutes after having a dose of omeprazole, you do not need to give them another dose.

What should I do if I accidentally give too much?

It is unlikely that you will cause harm if you give your child an extra dose of omeprazole by mistake. If you are worried that you may have given too much omeprazole, contact your doctor or local care team (details at end of leaflet). Have the medicine packet with you if you telephone for advice.

After the 4-week treatment period

After the 4-week study treatment period your baby's care will continue as normal. If further treatment is needed, you can speak to your baby's doctor or healthcare professional as normal.

Local care team contacts

(Name, phone number and contact email of health care professional)