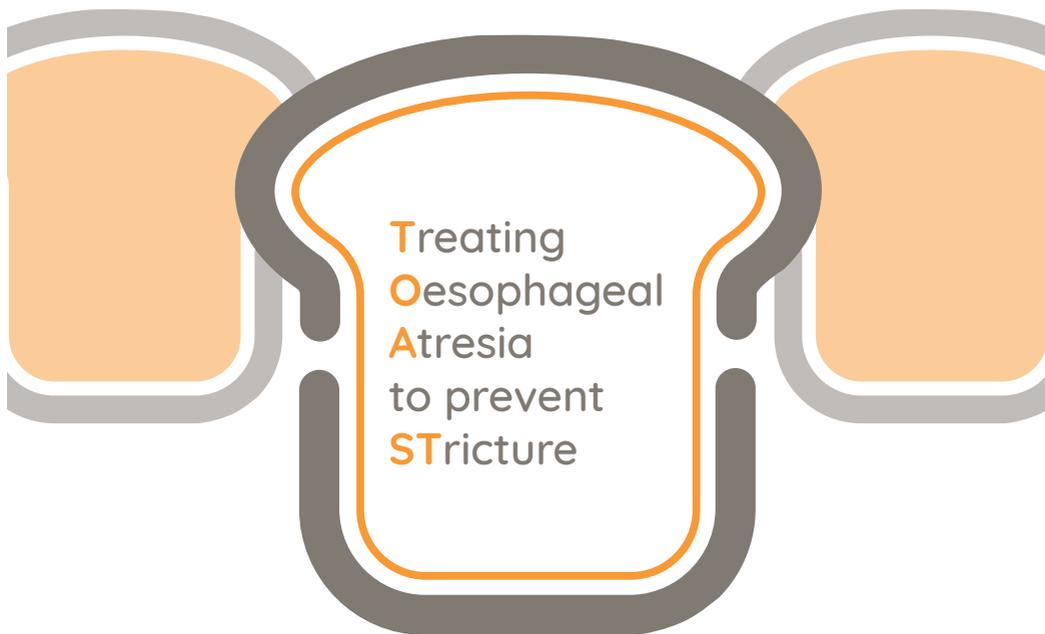

TOAST



TOAST Medication Guide (for Parents)

Local research team contact details:

or see back page of this booklet for
TOAST Study Team contact details.

TOAST Medication Guide (for Parents)

This guide explains how to prepare the TOAST medication to give to your baby, how to draw the medication into a syringe and tips for giving the medication to your baby. You can also see the Study Medication Video on our website:



www.npeu.ox.ac.uk/toast

Before you left hospital you should have been given a supply of TOAST medication for you to give your baby at home. This should last around 6 months. You will be given another box during one of your follow-up appointments at the hospital. If for any reason you run out of medication, please contact the local research team.

Preparing the TOAST Medication

In each full box you should find:

- 6 bottles containing powder in the red cap and the bottle. Each bottle is sealed within an aluminium foil pouch
- 6 dosing syringes
- 6 bottle adaptors
- 6 grey replacement caps.



This box can be stored at room temperature.

Once made up or 'reconstituted', the medication bottle should be stored in the fridge.

Make sure the TOAST medication is kept out of reach from children.

Before you can give TOAST medication to your baby, it needs to be made up, or 'reconstituted'. Follow the steps below to reconstitute the medication:

| | |
|---|---|
|  | <p>1. Open the box and take out one foil pouch. Open the pouch and take out the bottle.</p> |
|  | <p>2. Wash your hands and check that the tamper-evident seal on the bottle is still intact. If the seal looks damaged, do not use the medication, and contact the local research team straight away.</p> |
|  | <p>3. The bottle is a two-compartment system and contains powder both in the red cap and in the bottle. To combine the two powders, first shake the bottle for 10 seconds to loosen the powders.</p> |
|  | <p>4. Twist the red cap anticlockwise until the seal is broken. The powder and a red mixing disc will drop from the red cap into the bottle. The red mixing disc should remain in the bottle, and should not be removed after reconstitution.</p> |
|  | <p>5. Twist the red cap back to the original position, making sure it is securely fastened onto the bottle.</p> |
|  | <p>6. Shake the bottle vigorously for 10 seconds to mix the powders.</p> |

| | |
|---|--|
|  | <p>7. Tap the base of the bottle 3 times on a hard horizontal surface to make sure all powder is in the bottle and not in the cap.</p> |
|  | <p>8. The next step is to reconstitute the powder with tap water that has first been boiled and cooled. Remove the red cap from the bottle. Then using a suitable measuring device (such as the measuring cylinder provided), measure 64 ml of the boiled and cooled tap water and add this into the bottle*.</p> |
|  | <p>9. Securely fasten the red cap onto the bottle and shake vigorously for 30 seconds.</p> |
|  | <p>10. The final step is the placement of the syringe adaptor. To do this, remove the red cap and red ring and throw these away. Insert the colourless, transparent bottle adaptor, and replace the red cap with the grey plastic screw cap. Leave the medication at room temperature for 15 minutes before use, to reach its final consistency (it will become a liquid similar to cough medicine).</p> |

*Two measuring cylinders will be provided in the TOAST accessory pack when your baby is discharged from hospital. You can use the measuring cylinder to help measure the 64 ml cooled boiled water required to reconstitute the TOAST medication. They can be reused – wash and dry the measuring cylinder before the next use as you would a baby bottle. More measuring cylinders can be requested by contacting your local research team or the TOAST Study team, if required.

- **Once reconstituted, the medication should be stored in the fridge, and can be stored for up to 28 days.**
- **Please write the date the medication was reconstituted and the date that it should be discarded on the bottle label.**
- **After 28 days, even if there's some medication left, discard the medication by placing in a domestic bin, and start a new bottle.**



You can also keep track of when you should discard the medication on the paper TOAST Medication Log or TOAST fridge magnet. The TOAST app will send you a reminder on day 28 to discard the medication and reconstitute a new bottle.

If you accidentally leave your reconstituted TOAST medication at room temperature for a short time, please return the bottle to the fridge as soon as possible - it is still safe to give the medication to your baby. However, if the bottle is regularly stored at room temperature this will affect how well the medication works.

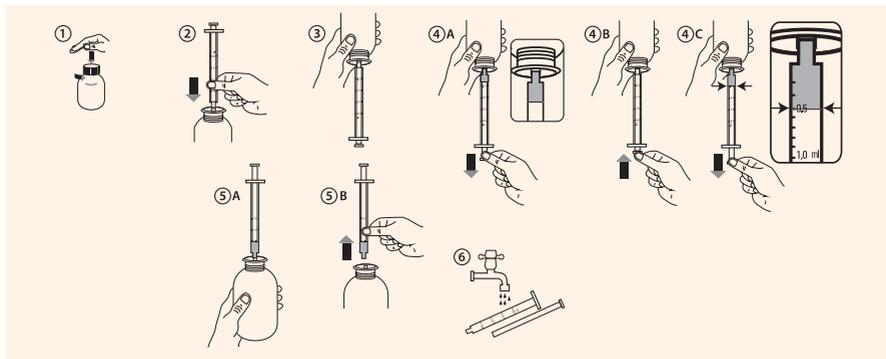
If your baby is admitted for a stay in hospital, we recommend taking a new unopened bottle of TOAST medication with you.

Dosing Chart

Check how much medication your baby should be taking based on their most recent weight and refer to the TOAST dosing chart below (or in the app) to make sure you are giving the correct amount. This weight could be from your routine clinic visit or visit with your health visitor or GP.

| Infant Weight Range | | Medication volume |
|---------------------|--------------------------|-------------------|
| (g) | (lb oz) | (ml) |
| 2000 – 2199 | 4 lb 7 oz – 4 lb 13 oz | 1.0 |
| 2200 – 2399 | 4 lb 14 oz – 5 lb 4 oz | 1.1 |
| 2400 – 2599 | 5 lb 5 oz – 5 lb 11 oz | 1.2 |
| 2600 – 2799 | 5 lb 12 oz – 6 lb 2 oz | 1.3 |
| 2800 – 2999 | 6 lb 3 oz – 6 lb 9 oz | 1.4 |
| 3000 – 3199 | 6 lb 10 oz – 7 lb 0 oz | 1.5 |
| 3200 – 3399 | 7 lb 1 oz – 7 lb 7 oz | 1.6 |
| 3400 – 3599 | 7 lb 8 oz – 7 lb 14 oz | 1.7 |
| 3600 – 3799 | 7 lb 15 oz – 8 lb 6 oz | 1.8 |
| 3800 – 3999 | 8 lb 7 oz – 8 lb 13 oz | 1.9 |
| 4000 – 4199 | 8 lb 14 oz – 9 lb 4 oz | 2.0 |
| 4200 – 4399 | 9 lb 5 oz – 9 lb 11 oz | 2.1 |
| 4400 – 4599 | 9 lb 12 oz – 10 lb 2 oz | 2.2 |
| 4600 – 4799 | 10 lb 3 oz – 10 lb 9 oz | 2.3 |
| 4800 – 4999 | 10 lb 10 oz – 11 lb 0 oz | 2.4 |
| 5000 – 5199 | 11 lb 1 oz – 11 lb 7 oz | 2.5 |
| 5200 – 5399 | 11 lb 8 oz – 11 lb 14 oz | 2.6 |
| 5400 – 5599 | 11 lb 15 oz – 12 lb 5 oz | 2.7 |
| 5600 – 5799 | 12 lb 6 oz – 12 lb 12 oz | 2.8 |
| 5800 – 5999 | 12 lb 13 oz – 13 lb 3 oz | 2.9 |
| 6000 – 6199 | 13 lb 4 oz – 13 lb 10 oz | 3.0 |
| 6200 – 6399 | 13 lb 11 oz – 14 lb 1 oz | 3.1 |
| 6400 – 6599 | 14 lb 2 oz – 14 lb 8 oz | 3.2 |
| 6600 – 6799 | 14 lb 9 oz – 14 lb 15 oz | 3.3 |
| 6800 – 6999 | 15 lb 0 oz – 15 lb 6 oz | 3.4 |
| 7000 – 7199 | 15 lb 7 oz – 15 lb 13 oz | 3.5 |
| 7200 – 7399 | 15 lb 14 oz – 16 lb 5 oz | 3.6 |
| 7400 – 7599 | 16 lb 6 oz – 16 lb 12 oz | 3.7 |
| 7600 – 7799 | 16 lb 13 oz – 17 lb 3 oz | 3.8 |
| 7800 – 7999 | 17 lb 4 oz – 17 lb 10 oz | 3.9 |
| 8000 – 8199 | 17 lb 11 oz – 18 lb 1 oz | 4.0 |
| 8200 – 8399 | 18 lb 2 oz – 18 lb 8 oz | 4.1 |
| 8400 – 8599 | 18 lb 9 oz – 18 lb 15 oz | 4.2 |
| 8600 – 8799 | 19 lb 0 oz – 19 lb 6 oz | 4.3 |
| 8800 – 8999 | 19 lb 7 oz – 19 lb 13 oz | 4.4 |
| 9000 – 9199 | 19 lb 14 oz – 20 lb 4 oz | 4.5 |
| 9200 – 9399 | 20 lb 5 oz – 20 lb 11 oz | 4.6 |
| 9400 – 9599 | 20 lb 12 oz – 21 lb 2 oz | 4.7 |
| 9600 – 9799 | 21 lb 3 oz – 21 lb 9 oz | 4.8 |
| 9800 – 9999 | 21 lb 10 oz – 22 lb 0 oz | 4.9 |
| 10000 – 10199 | 22 lb 1 oz – 22 lb 7 oz | 5.0 |
| 10200 – 10399 | 22 lb 8 oz – 22 lb 14 oz | 5.1 |
| 10400 – 10599 | 22 lb 15 oz – 23 lb 5 oz | 5.2 |
| 10600 – 10799 | 23 lb 6 oz – 23 lb 12 oz | 5.3 |
| 10800 – 10999 | 23 lb 13 oz – 24 lb 3 oz | 5.4 |
| 11000 – 11199 | 24 lb 4 oz – 24 lb 11 oz | 5.5 |
| 11200 – 11399 | 24 lb 12 oz – 25 lb 2 oz | 5.6 |
| 11400 – 11599 | 25 lb 3 oz – 25 lb 9 oz | 5.7 |
| 11600 – 11799 | 25 lb 10 oz – 26 lb 0 oz | 5.8 |
| 11800 – 11999 | 26 lb 1 oz – 26 lb 7 oz | 5.9 |
| 12000 – 12199 | 26 lb 8 oz – 26 lb 14 oz | 6.0 |

Measuring your dose with the syringe



1. Shake the bottle for 20 seconds immediately prior to each use. To open the bottle, press the grey cap down and turn it anticlockwise. Do not remove the white cap portion.
2. In your box, you will find six 5 ml syringes. Take the syringe and place it firmly into the adaptor opening.
3. Turn the bottle upside down.
4. Keeping the bottle upside down, pull the plunger down to draw a small amount of medication into the syringe. Then push the plunger upward to send the medication back into the bottle, in order to remove any bubbles. Finally, pull the plunger down to draw the amount of medication into the syringe that your baby should be taking. Make sure that the top flat edge of the plunger is positioned in line with the volume you are measuring.
5. Turn the bottle back so it is the right way up and remove the syringe from the adaptor by twisting the syringe gently. You can now give the medication to your baby by placing the end of the syringe inside your baby's mouth against their cheek and pushing the plunger slowly. This is similar to giving any over-the-counter medications such as liquid paracetamol to your baby. After you have given your baby the medication, close the bottle with the grey plastic screw cap – leave the bottle adaptor in the bottle - and return the bottle to the fridge. Note: it is normal for the red mixing disc to be in the medication bottle during use – do not attempt to remove this from inside the bottle.
6. Wash the syringe with water and let it dry before you use it again. Please remember to record the medication on the TOAST app.

Tips for giving medication to your baby

The TOAST medication should be given to your baby once per day, at any time of day, until your baby is one year of age. As we all know, every baby is unique, and some take medicines more easily than others do. You may want to try different methods to find the best fit for you and your baby. You may find that the best method for your baby changes over time.

Different brands of omeprazole are available, and the TOAST medication may taste different to other brands prescribed. We advise parents not to taste the medication.

Syringe

Hold your child in an upright position. Place the syringe inside their mouth, against their cheek. Press the plunger down slowly and gradually release the medicine one or two drops at a time, giving your baby time to swallow. Some parents find the best time to give their baby their medication is just before, or alongside a milk feed.



Nasogastric Tube

If your baby has a nasogastric tube, you can give the medication through their tube.

Spoon

Once you have drawn up the correct amount of medication into a syringe, you can transfer this onto a baby-friendly spoon to feed to your baby a few drops at a time. You can alternate spoons of medication with your baby's usual milk, or solid foods if your baby has started weaning. Sometimes babies who are a few months old want to hold the spoon themselves. If this is making it difficult to give them their medication, you can try giving them a different spoon to hold or play with at the same time.



What to do if your baby misses a dose

If you forget to give your baby a dose, do not give a double dose the next day to make up for a forgotten dose. Just give your baby the usual dose the next day, and record on the TOAST app that a dose was missed.

We expect that babies may occasionally miss doses or have breaks in having their medication over the course of 12 months. This does not mean you have to withdraw from the trial. You can use the TOAST app to record that the TOAST medication has been missed. The TOAST Study team would like to understand how often this happens and why, so they can properly interpret the final results of the study.

Symptomatic reflux treatment pathway

We have worked closely with clinicians to develop a reflux management plan. You can find a copy of this in the TOAST Parent Information Leaflet, or on the TOAST website. If your baby is experiencing additional symptoms of reflux, please get in touch with the clinical team who are caring for your baby. This does not mean that you have to withdraw from the trial.

Any questions?

If your supply of medication is getting low, or you have any questions or need advice, please contact your local research team or the TOAST Study team.

***Thank you for taking the time to read
this medication guide***

Contact Information:

TOAST Study Team

NPEU Clinical Trials Unit,
National Perinatal Epidemiology Unit, University of Oxford,
Old Road Campus, OXFORD, OX3 7LF

☎ 01865 289278 ✉ toast@npeu.ox.ac.uk 🌐 www.npeu.ox.ac.uk/toast



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www.npeu.ox.ac.uk/toast



National Institute for
Health and Care Research

UNIVERSITY OF
Southampton



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