

Esomeprazole enteric coated granules for suspension **Gastroesophageal Reflux Disease treatment for Children**

Esomeprazole is a medication called a proton pump inhibitor (PPI). It is used in the treatment of reflux oesophagitis (discomfort caused when stomach contents are brought up after feeding) and stomach ulcers. During reflux the stomach acid causes irritation of the food pipe (oesophagus), which is often painful. Esomeprazole is used to reduce the amount of acid made by the stomach, which helps to reduce the irritation and protect the food pipe. Taking esomeprazole can be an important part of the treatment of gastroesophageal reflux by helping to reduce the irritation.

If your child has been switched from liquid omeprazole to esomeprazole this is because the liquid omeprazole is less clinically effective:

PPIs in the liquid form are, to a great extent destroyed when they reach the stomach, due to the stomach acid. For this reason, the granules in the esomeprazole formulation are specially coated to protect the medicine from the stomach acid. Liquid PPI preparations do not have this special coating, which means it will not work so well for your child.

Esomeprazole granules are indicated for infants with a nasogastric tube or who cannot take dispersible tablets. Once the infant is able to take solid food the healthcare professional will review whether to continue treatment. If continuation is necessary they will change the prescription from the granules to orodispersible tablets.

When and how should I give the medicine:

- Esomeprazole is normally taken once a day.
- Esomeprazole can be given with food or on an empty stomach.

Giving esomeprazole as the branded product, Nexium®, the granule formulation can be made into a suspension for administration to babies or small children under the age of 1 who have a nasogastric tube. Your pharmacist or doctor can advise how to give esomeprazole granules, as there are several different methods available depending on the age and condition of your child. See table below with dosing and administration directions. Each sachet contains enteric coated granules. The special coating helps to protect the medication from the stomach acid.

It is important the granules are not crushed, as this stops the medicine from working properly.

When the granules are prepared as a suspension according to the directions below, they can be administered down an enteral feeding tube.

Esomeprazole enteric coated granules are a suitable formulation for dosing in children with enteral feeding tubes.

The contents of the sachet(s) can be mixed with 15mL of cool water per sachet. Do not use fizzy water. Stir the contents well until the granules have dispersed and leave for a few minutes to thicken. Stir again and drink within 30 minutes.

Caution: product continues to thicken on standing and granules will turn black.

Use within 30 minutes of preparation.

The granules should not be chewed or crushed. Rinse with a little water and then give to your child, to obtain all granules.

The dose for children is based on the child's weight and the doctor/ clinician will decide the correct dose.



Dosing table: Esomeprazole granules for children with enteral feeding tubes (6Fr or larger)

Child's weight	Dose and frequency	How to make up dose using 10mg esomeprazole granule sachet
Infant < 1 age- use esomeprazole granules as the branded product Nexium®		
3kg to 5 kg	2.5mg once daily	Mix contents of one 10mg esomeprazole (Nexium®) granule sachet with 15ml of water, stir, leave for a few minutes to thicken, stir again, draw 3.75ml of the suspension into a syringe to make the 2.5mg dose. Inject through the enteral feeding tube. Shake and flush any remaining contents through the enteral feeding tube with water. The unused suspension should be discarded.
> 5kg to 7.5kg	5mg once daily	Mix contents of one 10mg esomeprazole (Nexium®) granule sachet with 15ml of water, leave for a few minutes to thicken, stir again, draw 7.5ml of the suspension into a syringe to make the 5mg dose. Inject through the enteral feeding tube. Shake and flush any remaining contents through the enteral feeding tube with water. The unused suspension should be discarded.
> 7.5kg	10mg once daily	Mix contents of one 10mg esomeprazole (Nexium®) granule sachet with 15ml of water, leave for a few minutes to thicken, stir again, draw 15ml of the suspension into a syringe to make the 10mg dose. Inject through the enteral feeding tube. Shake and flush any remaining contents through the enteral feeding tube with water.
Children aged 1 to 11 years		
< 20kg	10mg once daily	Mix contents of one 10mg esomeprazole granule sachet with 15ml of water, leave for a few minutes to thicken, stir again, draw 15ml of the suspension into a syringe to make the 10mg dose. Inject through the enteral feeding tube. Shake and flush any remaining contents through the enteral feeding tube with water.
≥ 20kg	10mg once daily	Mix contents of one 10mg esomeprazole granule sachet with 15ml of water, leave for a few minutes to thicken, stir again, draw 15ml of the suspension into a syringe to make the 10mg dose. Inject through the enteral feeding tube. Shake and flush any remaining contents through the enteral feeding tube with water.
	20mg once daily	Mix contents of two 10mg esomeprazole granule sachets with 30ml of water, leave for a few minutes to thicken, stir again, draw 30ml of the suspension into a syringe to make the 20mg dose. Inject through the enteral feeding tube. Shake and flush any remaining contents through the enteral feeding tube with water.

Whilst on esomeprazole you can give your child medicines that contain paracetamol or ibuprofen, but for other medicines bought over the counter, including complementary and herbal medicines, check with your doctor or pharmacist about possible interactions.

What to do if a dose is missed:

If you miss a dose of esomeprazole, it can be taken as soon as you remember. Do not take the dose if there is less than 6 hours before the next dose; just take the next dose as normal. Do not double-up on any doses.

When should the medicine start working:

Esomeprazole starts working straight away and your child should start to have less discomfort and less reflux. It may take up to 4 weeks for a PPI to work fully, so your child may still have some symptoms during this time. If you are not sure whether the medicine is working, contact your doctor.



Child vomits:

If the child vomits less than 30 minutes after giving esomeprazole, give them another dose. If the child vomits more than 30 minutes after giving esomeprazole, do not give another dose, wait for the next normal dose. If the child is sick again, seek advice from your doctor or pharmacist.

Are there any possible side effects:

We use medicines to make our children better, but sometimes they have other effects that we don't want. Esomeprazole is a safe medicine, and most children can take it without having any side effects. However, side effects can occur. Some of these are not serious and will go away with time or after the dose has been changed. Others are more serious and require you to check with your doctor.

Side effects you MUST do something about:

If your child develops a rash, swelling of the face, lips, tongue or throat, or has difficulty breathing or swallowing, they may be allergic to esomeprazole. Contact your doctor or take your child to hospital straight away.

ALLERGIC REACTION: Stop medicine and contact your doctor or take your child to hospital straight away.

Other side effects you need to know about:

Your child may get the following side-effects when they first start taking esomeprazole. They should wear off as your child's body gets used to the medicine. If they are still a problem after a week or so, contact your doctor.

- Your child may have stomach pain, feel sick or be sick (vomit) or they may get diarrhoea, wind (flatulence) or constipation (difficulty doing a poo). It may help to give each dose with some food.
- Your child may feel light-headed or dizzy.
- Some children feel sleepy, but some find it hard to get to sleep at night. If this is still a problem after about 2 weeks, contact your doctor.
- They may get headaches.

There may sometimes be other side effects that are not listed above. If you notice anything unusual and are concerned, contact your doctor.

Storing the medicine:

It is important to keep esomeprazole locked away out of reach of children. Do not keep the sachets in the bathroom, near the kitchen sink or in other damp, warm places because this may make them less effective. Store in a cool, dry place, away from heat and direct light.

Important: Keep all medicines out of reach of children.