

PediPPI

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PediPPI?

PediPPI contains the active ingredient omeprazole. PediPPI is used to treat the following conditions:

- Reflux oesophagitis
- Peptic ulcers
- Peptic ulcers associated with *Helicobacter pylori* infection
- Peptic ulcers associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)
- Zollinger-Ellison Syndrome
- Children over 1 month of age: Reflux oesophagitis, symptoms of gastro-oesophageal reflux disease (GORD).

For more information, see Section [1. Why am I using PediPPI?](#) in the full CMI.

2. What should I know before I use PediPPI?

Do not use if you have ever had an allergic reaction to omeprazole or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PediPPI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PediPPI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PediPPI?

- Take as much as advised to you by your doctor.
- For doses of ≤ 15 mg, the 2 mg/mL strength is recommended. For doses of 20 mg or 40 mg, the 4 mg/mL strength is suitable.
- Take on an empty stomach, at least 30 minutes before a meal.

More instructions can be found in Section [4. How do I use PediPPI?](#) in the full CMI.

5. What should I know while using PediPPI?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using PediPPI.• Tell your doctor if you become pregnant while you are taking PediPPI.• Tell your doctor if your reflux symptoms return after you stop taking PediPPI.
Looking after your medicine	<ul style="list-style-type: none">• Dry powder: Store below 25°C. Store in the original foil pouch to protect from light and moisture.• Reconstituted suspension: Store the reconstituted suspension in a refrigerator (2°C - 8°C). Store in the original container to protect from light. Keep the bottle tightly closed. It may be stored below 25°C for up to 2 days.

For more information, see Section [5. What should I know while using PediPPI?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are headache, stomach and/or bowel complaints, nausea or vomiting, skin reactions, swelling of hands/feet or ankles, jaundice, ulcers/blisters/bleeding, blood in urine or faeces, or serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PediPPI

Powder for oral suspension 2 mg/mL & 4 mg/mL

Active ingredient(s): omeprazole

Consumer Medicine Information (CMI)

This leaflet provides important information about using PediPPI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about PediPPI.**

Where to find information in this leaflet:

- [1. Why am I using PediPPI?](#)
- [2. What should I know before I use PediPPI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PediPPI?](#)
- [5. What should I know while using PediPPI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PediPPI?

PediPPI contains the active ingredient omeprazole.

PediPPI is a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

PediPPI is used to treat the following conditions:

Reflux oesophagitis

PediPPI is used to treat the symptoms of reflux oesophagitis or reflux disease in adults and in children. This can be caused by "washing back" (reflux) of food and acid from the stomach into the gullet (oesophagus). Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn. PediPPI is also used to help stop reflux oesophagitis coming back or relapsing.

Peptic ulcers

PediPPI is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

PediPPI is also used to help stop gastric or duodenal ulcers coming back.

PediPPI also helps to relieve upper abdominal pain or discomfort that is often, but not always, related to eating.

Peptic ulcers associated with *Helicobacter pylori* infection

Most people who have a peptic ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

When PediPPI is taken with antibiotics, they will kill *Helicobacter pylori* and let your peptic ulcer heal. When PediPPI is taken together with two antibiotics, they are more effective than taken one or two at a time. It is possible that the antibiotics may not always kill *Helicobacter pylori*. You may need further treatment.

Peptic ulcers associated with Non-steroidal Anti-inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs. These medicines are commonly taken to treat joint disease or arthritis. PediPPI is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

PediPPI is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

Children over 1 month of age

Reflux oesophagitis and treatment of symptoms of gastro-oesophageal reflux disease (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.

In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

2. What should I know before I use PediPPI?

Warnings

Do not use PediPPI if:

- you are allergic to omeprazole, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are taking cilostazol, a medicine used to treat intermittent claudication (cramp-like pain in one or both legs).

Check with your doctor if you:

- are allergic to proton-pump inhibitors
- have been diagnosed with osteoporosis
- have any problems with your liver
- have ever had a skin reaction after treatment with a medicine similar to omeprazole that reduces stomach acid

- take clopidogrel (medicine used to prevent blood clots), or medicines used to treat viral infections such as atazanavir and nelfinavir.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take PediPPI if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking any other medicines, including:

- cilostazol - a medicine used to treat intermittent claudication (cramp-like pain in one or both legs)
- warfarin and clopidogrel - medicines used to prevent blood clots
- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- phenytoin – a medicine used to treat epilepsy or fits
- digoxin - a medicine used to treat heart conditions
- diazepam - a medicine used to treat anxiety and some other conditions
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- St John's Wort - a herbal remedy used to treat mood disorders
- clarithromycin or rifampicin - medicines used to treat infections
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants
- methotrexate - a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer
- citalopram / escitalopram – medicines used to treat depression.

Some medicines may interfere with PediPPI and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PediPPI.

4. How do I use PediPPI?

How much to take

Your doctor will tell you how much medicine to take and how long to take it for. This will depend on your condition and how old you are.

For doses of ≤ 15 mg, the 2 mg/mL strength is recommended. For doses of 20 mg or 40 mg, the 4 mg/mL strength is suitable.

Adults

The dose of PediPPI is usually 20 mg a day, but may vary from 10 mg to 40 mg a day depending on what condition you are being treated for and how severe it is.

Children

The recommended dose in children over **1 month of age to 1 year of age** is 1 mg/kg once daily. Your doctor will calculate how much omeprazole your child should take. The recommended dose in children **over one year of age** is 10 mg once a day in children weighing 10 - 20 kg and 20 mg in children weighing more than 20 kg.

Follow the instructions provided and use PediPPI until your doctor tells you to stop.

When to take PediPPI

PediPPI should be taken at about the same time each day, preferably in the morning. Take on an empty stomach, at least 30 minutes before a meal. Keeping a regular time for taking PediPPI will help to remind you to take it.

How to prepare PediPPI and how to measure the dose

Please refer to section **INSTRUCTIONS FOR USE** at the end of this leaflet.

If you forget to take PediPPI

PediPPI should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much PediPPI

If you think that you have taken too much PediPPI, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26 - Australia**, or **0800 POISON** or **0800 764 766 - New Zealand**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using PediPPI?

Things you should do

You must use PediPPI exactly as your doctor has prescribed.

Remind any doctor, dentist or pharmacist you visit that you are using PediPPI.

Tell your doctor if you become pregnant while you are taking PediPPI.

Tell your doctor if your reflux symptoms return after you stop taking PediPPI.

Looking after your medicine

- Dry powder: Store below 25°C. Store in the original foil pouch to protect from light and moisture.
- Reconstituted suspension: Store the reconstituted suspension in a refrigerator (2°C - 8°C). Store in the original container to protect from light. Keep the bottle tightly closed. It may be stored below 25°C for up to 2 days.

Follow the instructions in the carton on how to take care of your medicine properly.

Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard the medicine 28 days from date of preparation.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>These are all mild side effects:</p> <ul style="list-style-type: none"> • constipation • nausea or vomiting • diarrhoea and wind (flatulence) • headache • stomach pain. <p>Some people may notice:</p> <ul style="list-style-type: none"> • skin rash, itchy skin • muscle pain or weakness • dizziness • "pins and needles" • changes in sleep patterns • mood changes, confusion or depression • increase in breast size (males) • fever • increased bruising • dry or sore mouth • blurred vision • increased sweating • hair loss • tremor. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing • shortness of breath or difficulty in breathing • skin reaction which may include rash, itching, redness, blistering or peeling of the skin • ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals • blood in the urine • swelling of hands, feet or ankles • signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite • skin reaction, especially in sun-exposed areas, with joint pain. <p>The following side effects are more likely to arise from the ulcer itself rather than the treatment:</p> <ul style="list-style-type: none"> • pain or indigestion during treatment with PediPPI • beginning to vomit blood or food • passing black (blood-stained) motions. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems (Australia). By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PediPPI contains

Active ingredient (main ingredient)	Omeprazole
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Sodium hydrogen carbonate• Potassium hydrogen carbonate• Sodium alginate• Maltitol• Mannitol• Sucralose• Xanthan gum• Vanilla flavour (for omeprazole 2 mg only)• Menthol flavour• Titanium dioxide• Sodium benzoate• Sodium methyl parahydroxybenzoate

Do not take this medicine if you are allergic to any of these ingredients.

What PediPPI looks like

PediPPI is packed in an amber plastic bottle with powder, fitted with a red closure cap also containing powder, all enclosed in an aluminium foil pouch. Each pack also contains a bottle adapter, an oral dosing syringe and a replacement cap.

Each bottle contains 47 g of powder for oral suspension. Once reconstituted, the bottle contains 90 mL of oral suspension, of which 75 mL is intended for dosing and administration.

Before reconstitution: White / off-white / slightly yellow powder in a cap attached to a bottle containing white / off-white / slightly yellow powder, which may contain dark specks due to sweetener.

After reconstitution: White / off-white / brownish oral suspension. May contain dark specks due to sweetener.

Who distributes PediPPI

Distributed in New Zealand by:

BNM Group
39 Anzac Road
Browns Bay
Auckland 0753

Ph: 0800 565 633

This leaflet was revised in May 2022.

INSTRUCTIONS FOR USE

It is recommended that a pharmacist reconstitutes PediPPI oral suspension prior to its dispensing to the patient.

Preparing and taking the suspension

The container is two compartment system containing powder both in the cap and in the bottle. The two powders first need to be combined and are then to be reconstituted in water. A red mixing disk will drop into the medicine to help mix the powders and also mix the reconstituted suspension after addition of the water. It should remain in the bottle. The red cap is replaced by a grey cap after reconstitution.

Instructions for initial reconstitution

Combination of powder in cap and bottle

- Shake the bottle for 10 seconds to loosen the powder.
- Twist the red cap anti-clockwise (see arrow on cap) until the seal is broken to release the powder in the red cap into the bottle.
- Twist the red cap back to the original position, securely fastening the red cap onto the bottle.

Reconstitution of the powder

- Shake the bottle vigorously for 10 seconds to mix the powders.
- Tap the base of the bottle three times on a hard-horizontal surface to make sure all powder is in the bottle and not in the cap.
- Remove the red cap from the bottle.
- Add 64 mL of water by using a suitable measuring device up to the line on the label.
- Securely fasten the red cap onto the bottle and shake vigorously for 30 seconds.

Placement of syringe adaptor

- Remove the red cap and red ring and throw away.
- Insert the colourless, transparent bottle adaptor and replace the red cap with the grey plastic screw-cap.
- Leave for 15 minutes for product to reach final consistency.

The reconstituted suspension will be a white / off-white / brownish suspension. It may contain dark specks due to the sweetener.

Measuring your dose

Instructions for use of the syringe

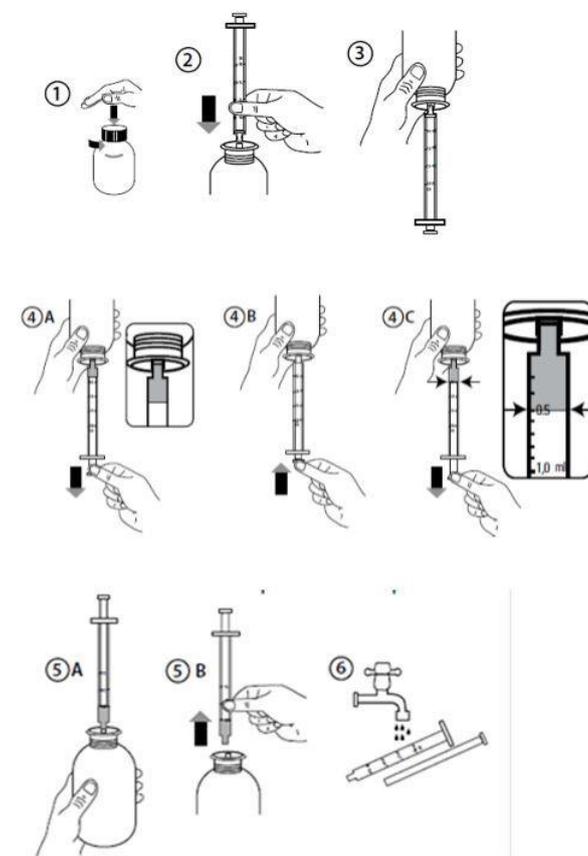
1. Shake for 20 seconds immediately prior to each use.
2. To open the bottle, press the grey cap down and turn it anti-clockwise (Figure 1). Do not remove the white cap portion.
3. Take the syringe and put it into the adaptor opening (Figure 2).
4. Turn the bottle upside down (Figure 3).
5. Fill the syringe with a small amount of suspension 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 graduation mark corresponding to the quantity in millilitres (mL) prescribed by your doctor.

The top flat edge of the piston 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 into the mouth of the patient and push the plunger slowly back in to take the medicine. The suspension will be released slowly while the last portion will be released faster due to reduced resistance in the tip of the syringe.
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 suspension during use; do not attempt to remove it.



Instruction for administration via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes

Ensure that the enteral feeding tube is free from obstruction before administration.

1. Flush the enteral tube with 5 mL of water.
2. Administer the required dose of omeprazole oral suspension with a suitable measuring device.
3. Flush the enteral tube with 5 mL of water.

This product is compatible for use with polyurethane and PVC nasogastric (NG) and percutaneous endoscopic gastrostomy (PEG) tubes of size 6 Fr to 16 Fr. For the smallest diameter tubes (6 Fr) a smaller flush volume of 2 mL may be used to support the use in very young children where fluid intake restriction may be of relevance.