Package leaflet: information for the patient

PEDIPPI 4mg/ml, Powder for Oral Suspension
Omeprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (See section 4.)

What is in this leaflet:

1. What Pedippi Oral Suspension is and what it is used for

The name of your medicine is Pedippi 4mg/ml Oral Suspension (called Pedippi Oral Suspension in this leaflet).

Pedippi Oral Suspension contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Omeprazole is commonly used to treat the following conditions:

In adults:

• '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.
• Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
• Ulcers which are infected with bacteria called '*Helicobacter pylori'*. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
• Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Omeprazole can also be used to stop ulcers from forming if you are taking NSAIDs.

In children:

Children over 1 month of age:

• '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.

Children over 4 years of age and adolescents:

• Ulcers which are infected with bacteria called '*Helicobacter pylori'*. If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

Your doctor will tell you why you have been given this medicine.

2. What you need to know before you take Pedippi Oral Suspension

Do not take Pedippi Oral Suspension
• If you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6).
• If you are allergic to medicines containing other proton pump inhibitors (eg pantoprazole, lansoprazole, rabeprazole, esomeprazole).
• If you are taking a medicine containing nelfinavir (used for HIV infection)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Pedippi Oral Suspension.

Warnings and precautions

Talk to your doctor or pharmacist before taking Omeprazole.

Omeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Pedippi Oral Suspension or while you are taking it, talk to your doctor straight away:
• You lose a lot of weight for no reason and have problems swallowing.
• You get stomach pain or indigestion.
• You begin to vomit food or blood.
• You pass black stools (blood-stained faeces).
• You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
• You have severe liver problems.
• You have ever had a skin reaction after treatment with a medicine similar to Omeprazole that reduces stomach acid
• You are due to have a specific blood test (Chromogranin A)

If you take Omeprazole on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking a proton pump inhibitor like Omeprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Omeprazole. Remember to also mention any other ill-effects like pain in your joints.

When taking omeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Children
Some children with chronic illnesses may require long-term treatment although it is not recommended. Do not give this medicine to children under 1 month of age.

Other medicines and Pedippi Oral Suspension
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. 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.

Do not take Omeprazole if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking any of the following medicines:
• Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus)
• Digoxin (used to treat heart problems)
• Diazepam (used to treat anxiety, relax muscles or in epilepsy)
• Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Omeprazole
• Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Omeprazole
• Rifampicin (used to treat tuberculosis)
• Atazanavir (used to treat HIV infection)
• Tacrolimus (in cases of organ transplantation)
• St John's wort (*Hypericum perforatum*) (used to treat mild depression)
• Cilostazol (used to treat intermittent claudication)
• Saquinavir (used to treat HIV infection)
• Clopidogrel (used to prevent blood clots (thrombi))
• Erlotinib (used to treat cancer)
• Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Omeprazole treatment.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Omeprazole to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Pedippi Oral Suspension with food and drink
You should take Pedippi Oral Suspension without food on an empty stomach.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. Your doctor will decide whether you can take Omeprazole if you are breastfeeding.

Driving and using machines
Omeprazole is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Pedippi Oral Suspension contains maltitol, potassium, sodium, sodium methyl parahydroxybenzoate and sodium benzoate.
- **Maltitol**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

- **Sodium**. This medicine contains 17.2 mg of sodium (main component of cooking/table salt) in each ml or 86 mg of sodium per 5ml dose. This 5ml dose is equivalent to 4.3% of the recommended maximum daily dietary intake of sodium for an adult.
- **Potassium**. This medicine contains 1.39 mmol (or 54.3 mg) potassium per ml or 6.95 mmol (or 271.5 mg) potassium per 5ml dose. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
- **Sodium methyl parahydroxybenzoate**. May cause allergic reactions (possibly delayed).
- **Sodium benzoate**. This medicine contains 25 mg sodium benzoate in each 5ml dose.

3. How to take Pedippi Oral Suspension

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

The recommended dose is given below.

Use in adults

To treat symptoms of GORD such as **heartburn and acid regurgitation:**

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is 10 mg once a day.
- If your gullet has not been damaged, the usual dose is 10 mg once a day.

To treat **ulcers in the upper part of the intestine** (duodenal ulcer):

- The recommended dose is 20 mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks if your ulcer has not yet healed.
- If the ulcers do not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

To treat **ulcers in the stomach** (gastric ulcer):

- The recommended dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcers do not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

To **prevent the duodenal and stomach ulcers** from coming back:

- The recommended dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

To treat **duodenal and stomach ulcers caused by NSAIDs** (Non-Steroidal Anti-Inflammatory Drugs):

- The recommended dose is 20 mg once a day for 4–8 weeks.

To **prevent duodenal and stomach ulcers** if you are taking **NSAIDs:**

- The recommended dose is 20 mg once a day.

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- The recommended dose is 20 mg Omeprazole twice a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole.

Use in children and adolescents

To treat symptoms of GORD such as **heartburn and acid regurgitation**:

- Children over 1 month of age may take Omeprazole. The dose for children is based on the child's weight and the doctor will decide the correct dose based on the following:

Age	Weight	Posology
1 month to 1 year of age	-	1 mg/kg once daily. Doses above 1.5 mg/kg/day have not been studied.
≥ 1 year of age	10-20 kg	10 mg once daily. The dose can be increased to 20 mg once daily if needed.
≥ 2 years of age	> 20 kg	20 mg once daily. The dose can be increased to 40 mg once daily if needed.

** The 2 mg/ml and 4 mg/ml strengths are equivalent with respect to buffering capacity (same amount of buffer on a ml basis).

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- Children aged over 4 years may take Omeprazole. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

Taking this medicine
- This medicine contains 20mg (Pedippi 4mg/ml Oral Suspension) in each 5 millilitre (5ml) of suspension.
- Take this medicine by mouth.
- It is recommended that you take your dose of medicine in the morning.

- This medicine should be taken on an empty stomach, at least 30 minutes before a meal.
- Use the dosing device provided to measure the correct dose (see Measuring your dose).
- A glass of water may be taken after taking the dose.
- This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes.
- Instructions for use via NG or PEG tube:
    - Ensure that the enteral feeding tube is free from obstruction before administration.
    - Flush the enteral tube with 5mL of water
    - Administer the required dose of Pedippi Oral Suspension with a suitable measuring device.
    - Flush the enteral tube with 5mL of water
- This product can be used with Polyurethane and PVC nasogastric (NG) and percutaneous endoscopic gastrostomy (PEG) tubes of size 6 Fr to 16 Fr.

Preparing and taking the suspension

The container is a 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 constituted in water. A red mixing disk will drop into the medicine to help mix the powders and also mix the constituted suspension after addition of the water. It should remain in the bottle. The red cap is replaced by a grey cap after constitution. It is recommended that a pharmacist constitutes Pedippi Oral Suspension prior to its dispensing to the patient.

Instructions for initial constitution.

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.

Constitution of the powder

- Shake the bottle vigorously for ten 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 64ml 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 fifteen minutes for product to reach final consistency.

Measuring your dose

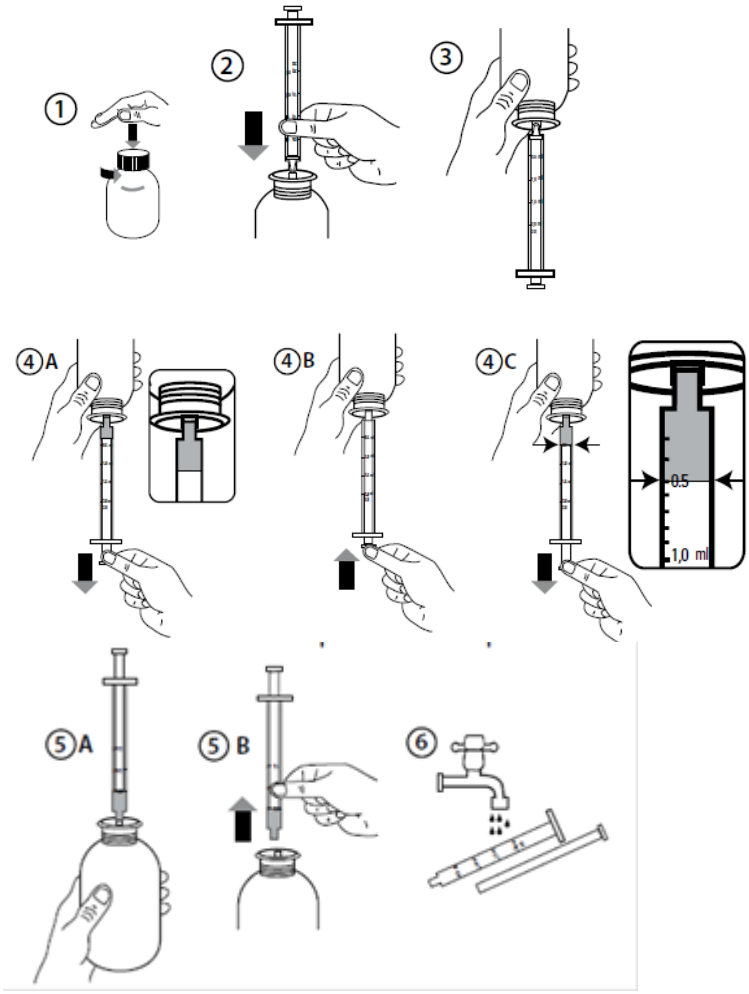
Instructions for use of the syringe

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.



If you take more Pedippi Oral Suspension than you should

If you take more of this medicine than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Pedippi Oral Suspension

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Pedippi Oral Suspension

Do not stop taking Omeprazole without first talking to your doctor or pharmacist.

If you have further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following rare but serious side effects, stop taking Pedippi Oral Suspension and contact a doctor immediately:
• Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
• Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
• Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Other side effects include:

Common side effects (may affect up to 1 in 10 people)
• Headache.
• Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
• Feeling sick (nausea) or being sick (vomiting).
• Benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people)
• Swelling of the feet and ankles.
• Disturbed sleep (insomnia).
• Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
• Spinning feeling (vertigo).
• Changes in blood tests that check how the liver is working.
• Skin rash, lumpy rash (hives) and itchy skin.
• Generally feeling unwell and lacking energy.

Rare side effects (may affect up to 1 in 1,000 people)
• Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
• Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
• Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
• Feeling agitated, confused or depressed.
• Taste changes.
• Eyesight problems such as blurred vision.
• Suddenly feeling wheezy or short of breath (bronchospasm).
• Dry mouth.
• An inflammation of the inside of the mouth.
• An infection called "thrush" which can affect the gut and is caused by a fungus.
• 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).
• Severe kidney problems (interstitial nephritis).
• Increased sweating.

Very rare side effects (may affect up to 1 in 10,000 people)

• Changes in blood count including agranulocytosis (lack of white blood cells).
• Aggression.
• Seeing, feeling or hearing things that are not there (hallucinations).
• Severe liver problems leading to liver failure and inflammation of the brain.
• Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
• Muscle weakness.
• Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)
• Inflammation in the gut (leading to diarrhoea).
• If you are on Omeprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
• Rash, possibly with pain in the joints.

Pedippi Oral Suspension may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance, Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pedippi Oral Suspension

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Dry Powders: Do not store above 25°C. Store in the original foil pouch in order to protect from light and moisture.
- Following constitution: Store in a refrigerator (2°C - 8°C). Store in the original container in order to protect from light. Keep the bottle tightly closed. The constituted suspension has a shelf life of 28 days. After this time, any remaining suspension should be discarded. For up to 2 days the suspension may be stored below 25°C.
- Do not use Pedippi Oral Suspension if you notice anything wrong with the appearance of the medicine (See section 6). Tell your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Pedippi Oral Suspension contains

- The active substance is omeprazole. Each ml of oral suspension contains 4mg of omeprazole
- The other ingredients are Sodium hydrogen carbonate (E500), Potassium hydrogen carbonate (E501), Sodium alginate (E401), Maltitol (E965), Mannitol (E421), Sucralose (E955), Xanthan gum (E415), Natural Mint Flavouring containing Gum Arabic / Acacia Gum (E414), Titanium dioxide (E171), Sodium benzoate (E211), Sodium methyl parahydroxybenzoate (E219)

What Pedippi Oral Suspension looks like and contents of the pack

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

Pack:
Amber plastic (PET) bottle with powder fitted with a red Polypropylene (PP) closure cap containing powder, all enclosed in an aluminium foil pouch.

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

Each pack also contains an opaque PP oral dosing syringe (5 ml, graduated at each 1ml and intermediate marks every 0.1ml) with white HDPE plunger, colourless, transparent LDPE press-in bottle adaptor and grey PP replacement cap.

Pack: 1 or 2 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Xeolas Pharmaceuticals Limited,
Hamilton Building,
DCU, Glasnevin,
Dublin 9,
IRELAND.

Distributor: Athena Pharmaceuticals Ltd, 4045 Kingswood Road, Citywest Business Campus, Co. Dublin, IRELAND.

Other sources of information

This leaflet is also available in other formats for blind and partially-sighted patients.
For large print and Braille, please go to www.xpil.medicines.org.

This leaflet was last revised in March 2023.

Post- Approval Revision History

Date	Rev	Details	Variation Ref
2 Aug 2022	R0	Approved PL for Ireland utilizing core PL	N/A
30 Mar 2023	R1	Implementation PSUSA/00002215/202204	NL/H/4504/002/ IA/019