Omeprazole ADVZ

Omeprazole powder for oral suspension

First Registered Omeprazole Suspension in Australia*

The only PPI^ formulation approved for use in babies over 1 month[1]

Scan QR to check instruction for use video

Available in 2 mg/mL oral suspension

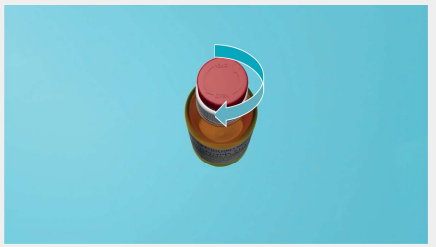
^ Proton-pump inhibitor

Instruction for constitution leaflet
(recommended to be undertaken by pharmacy staff prior to dispensing to the patient)

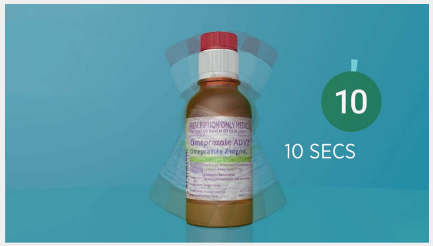
1. The contents of the carton include a bottle with powder in itself and its cap sealed in an aluminium foil pouch, a 5ml oral dosing syringe, a bottle adapter, a grey child-resistant cap and a patient information leaflet

2. The first step is to combine the powders. Shake the bottle for 10 seconds to loosen the powder in both the cap and the bottle.

3. Twist the red cap anticlockwise to break the seal, releasing the powder from the cap into the bottle. A red mixing disc will drop into the bottle. It should not be removed as it will assist in mixing the powders and constituted suspension.



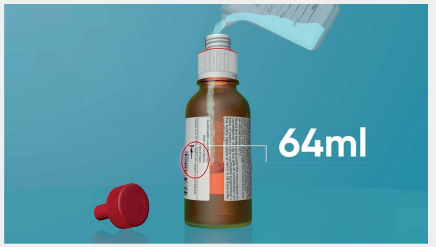
4. The red cap should be twisted back to the original position, making sure it is securely fastened to the bottle.



5. Shake the bottle vigorously for 10 seconds to mix the powders.

6. Tap the bottle 3 times on a hard horizontal surface to make sure all the powder is in the bottle and not in the cap.

7. The second step is the constitution of the powder. The red cap should first be removed from the bottle.



8. Using a suitable measuring device, 64ml of potable water should be added – taking the contents to roughly the level indicated on the bottle label.

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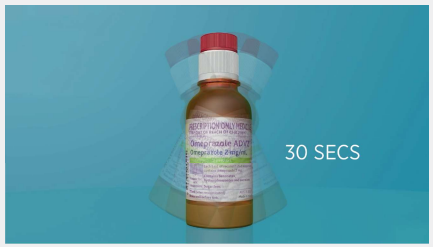
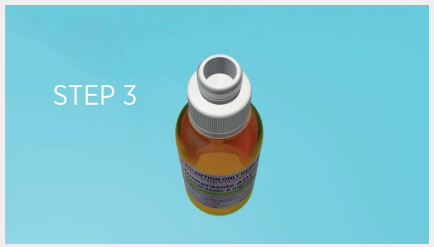


9. The red cap should be securely replaced, and the bottle shaken vigorously for 30 seconds.



10. The last step is the placement of the syringe adaptor. The red cap and red ring should be removed and thrown away.

11. The bottle adaptor should be inserted into place.

12. The bottle should then be capped with the grey plastic screw cap.

13. The bottle should then be left for 15 minutes to reach its final consistency.

Scan the QR code to check the video on instruction for constitution

Please check product information and/or patient information leaflet for more information

MINIMUM PRESCRIBING INFORMATION - Omeprazole powder for oral suspension 2 mg/mL & 4 mg/mL.

Presentation: Omeprazole ADVZ 2 mg/mL powder for oral suspension, Omeprazole ADVZ 4 mg/mL powder for oral suspension.

Indication: Omeprazole ADVZ is indicated for: **Adults :** Treatment of duodenal ulcers; Prevention of relapse of duodenal ulcers; Treatment of gastric ulcers; Prevention of relapse of gastric ulcers; In combination with appropriate antibiotics, *Helicobacter pylori (H. pylori)* eradication in peptic ulcer disease; Treatment of NSAID-associated gastric and duodenal ulcers; Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk; Treatment of reflux oesophagitis; Long-term management of patients with healed reflux oesophagitis; Treatment of symptomatic gastro-oesophageal reflux disease (GORD). **Paediatric use :** *Children over 1 month of age :* Treatment of reflux oesophagitis; Symptomatic treatment of heartburn and acid regurgitation in GORD. *Children over 4 years of age and adolescents:* In combination with antibiotics in treatment of duodenal ulcer caused by *H. pylori.* **Dosage and administration:** 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 Omeprazole ADVZ is usually 20 mg a day, but may vary from 10 mg to 40 mg a day depending on what condition is 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. 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. Please check full product information for complete information of dosage and administration. **Warnings & Precautions for use:** Concomitant administration of omeprazole and medicines such as atazanavir and nelfinavir is not recommended. Concomitant use of omeprazole and clopidogrel should be avoided. **Pregnancy and lactation: Pregnancy:** Results from three prospective epidemiological studies indicate no adverse effects of omeprazole on pregnancy or on the health of the foetus/newborn child. Omeprazole can be used during pregnancy. **Breast-feeding:** Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.Undesirable effects: **Blood and lymphatic system disorders** Rare: Leukopenia, thrombocytopenia, agranulocytosis, pancytopenia Immune system disorders Rare: Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock **Metabolism and nutrition disorders** Rare: Hyponatraemia Very rare: Hypomagnesaemia, severe hypomagnesaemia may result in hypocalcaemia. Hypomagnesaemia may also result in hypokalaemia. **Psychiatric disorders** Uncommon: Insomnia Rare: Agitation, aggression, confusion, depression, hallucinations **Nervous system disorders** Common: Headache Uncommon: Dizziness, paraesthesia, somnolence Rare: Taste disturbance **Eye disorders** Rare: Blurred vision **Ear and labyrinth disorders** Uncommon: Vertigo **Respiratory, thoracic and mediastinal disorders** Rare: Bronchospasm **Gastrointestinal disorders** Common: Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting Rare: Dry mouth, stomatitis, gastrointestinal candidiasis, microscopic colitis **Hepatobiliary disorders** Uncommon: Increased liver enzymes Rare: Hepatitis with or without jaundice, hepatic failure, encephalopathy in patients with pre-existing liver disease **Skin and subcutaneous tissue disorders** Uncommon: Dermatitis, pruritus, rash, urticaria Rare: Alopecia, photosensitivity, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS). **Musculoskeletal, connective tissue and bone disorders** Rare: Arthralgia, myalgia, muscular weakness **Renal and urinary disorders** Rare: Interstitial nephritis Reproductive system and breast disordersRare: Gynaecomastia **General disorders and administration site conditions.**

Uncommon: Malaise Rare: Increased sweating, peripheral oedema (Please refer to SPC for further information).

Medicine schedule: Schedule 4: Prescription only medicine

Marketing Authorisation number – 391771 - OMEPRAZOLE ADVZ omeprazole 2 mg/mL powder for suspension bottle,
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Sponsor: Boucher & Muir Pty Ltd t/a ADVANZ PHARMA (Australia); Level 9, 76 Berry Street, North Sydney NSW 2060, Ph: 1800 627 680

Date of first approval: 28th April 2023

Adverse events should be reported to the local regulatory authority. Reporting forms are available at https://www.tga.gov.au/. You can also report adverse event to ADVANZ Pharma Medical Information via email at medinfo.au@advanzpharma.com

References
1 : Omeprazole ADVZ, Australia Product information. Last approved 28th April 2023
*https://www.tga.gov.au/search?keywords=omeprazole&submit=Search&page=4

PBS information: This product is not listed on the PBS

Please review product information before prescribing. Please call 02 9431 6333 or email enquiries.au@advanzpharma.com for product information or for any other query.

ADVANZ PHARMA

AU/Ome/PM/0003 | Date of preparation: February 2024