Omeprazole ADVZ

Omeprazole powder for oral suspension

First Licensed Omeprazole Suspension in Australia*

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

- Sugar free[1]
- Ethanol free[1]
- Natural Mint and Natural Vanilla Flavor[1]
- Suitable for nasogastric (NG) tube[1]
- Suitable for percutaneous endoscopic gastrostomy (PEG) tube[1]
- Reconstituted suspension can be stored in refrigerator (2°C - 8°C) and used for up to 28 days[1]

Scan QR to check instruction for use video

Available in 2 mg/mL & 4 mg/mL oral suspension

^ Proton-pump inhibitor

Wholesaler product codes for product ordering	
Symbion	768677
CH2	2612959
API	195627
SIGMA	10033321
HCL	1183644

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,
391772 **-** OMEPRAZOLE ADVZ omeprazole 4 mg/mL powder for suspension bottle
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 in the PBS

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

ADVANZ PHARMA