OMEZ

40 mg
Lyophilized powder for solution for I.V infusion
omeprazole

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of powder for solution contains:
Active ingredient: 42.6 mg of omeprazole sodium equivalent to 40 mg of omeprazole.
Excipients: Disodium edetate, Sodium hydroxide (pH 9-10.5).

PHARMACEUTICAL FORM

Lyophilized powder for solution for I.V infusion
Physical characters:
before Reconstitution: White to off white powder
After Reconstitution: clear colorless to pale yellow solution

Therapeutic indications:
Omez 40 mg powder for solution for infusion for intravenous use is indicated as an alternative to oral therapy for the following indications:
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
- Treatment of Zollinger-Ellison syndrome

Posology and method of administration
Posology
Alternative to oral therapy
In patients where the use of oral medicinal products is inappropriate, Omez IV 40 mg once daily is recommended. In patients with Zollinger-Ellison Syndrome the recommended initial dose of omez given intravenously is 60 mg daily. Higher daily doses may be required and the dose should be adjusted individually. When doses exceed 60 mg daily, the dose should be divided and given twice daily.
Omez is to be administered in an intravenous infusion for 20-30 minutes.
For instructions on reconstitution of the product before administration, see section "Special precautions for disposal and other handling".

Special populations
- Impaired renal function

Dose adjustment is not needed in patients with impaired renal function. (see section "Pharmacokinetic Properties").
- Impaired hepatic function

Dr Marwa 28/9/2022

In patients with impaired hepatic function a daily dose of 10-20 mg may be sufficient (see section "Pharmacokinetic Properties").
- Older people (> 65 years old)

Dose adjustment is not needed in the elderly (see section "Pharmacokinetic Properties").
- Paediatric population

There is limited experience with Omeprazole 40 mg powder for solution for infusion for intravenous use in children.

Method of Administration
Omez is to be administered in an intravenous infusion for 20 - 30 minutes.
Once diluted the product should be used immediately.The entire contents of each vial (40 mg of omeprazole equivalent to 42.6 mg of omeprazole sodium) is to be dissolved in approximately 5 mL and then immediately diluted to 100 mL. Sodium chloride 9 mg/mL (0.9%) solution for infusion or dextrose 50 mg/mL (5%) solution for infusion must be used. The stability of omeprazole is influenced by the pH of the solution for infusion, which is why no other solvent or quantities should be used for dilution.

Preparation
1. With a syringe draw 5 mL of infusion solution from the 100 mL infusion bottle or bag.
2. Add this volume to the vial with the freeze-dried omeprazole, mix thoroughly making sure all omeprazole is dissolved.
3. Draw the omeprazole solution back into the syringe.
4. Transfer the solution into the infusion bag or bottle.
5. Repeat steps 1 - 4 to make sure all omeprazole is transferred from the vial into the infusion bag or bottle.

Alternative preparation for infusions in flexible containers
1. Use a double-ended transfer needle and attach to the injection membrane of the infusion bag. Connect the other needle-end from the vial with freeze-dried omeprazole.
2. Dissolve the omeprazole substance by pumping the infusion solution back and forward between the infusion bag and the vial.
3. Make sure all omeprazole is dissolved.

The solution for infusion is to be administered in an intravenous infusion for 20 - 30 minutes.
Any unused product or waste material should be disposed of in accordance with local requirements.

Contraindications
Hypersensitivity to omeprazole, substituted benzimidazoles or to any of the excipients listed in section "Composition".
Omeprazole like other proton pump inhibitors (PPIs) should not be used concomitantly with nelfinavir (see section "Interactions with other medicinal products and other forms of interaction").

Special warnings and precautions for use
Bone Fracture
Several published observational studies suggest that proton pump inhibitor (PPI) therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to the established treatment guidelines.

... of any alarm symptom (eg, significant unintentional weight loss, recurrent vomiting, dysphagia, ...sis or melena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment ...eviate symptoms and delay diagnosis.

Co-administration of atazanavir with proton pump inhibitors is not recommended (see Interactions with other medicinal products and other forms of interaction). If the combination of atazanavir with a proton pump inhibitor is judged unavoidable, close clinical monitoring (e.g virus load) is recommended in combination with an increase in the dose of atazanavir to 400 mg with 100 mg of ritonavir; omeprazole 20 mg should not be exceeded.

Omeprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy.

Omeprazole is a CYP2C19 inhibitor. When starting or ending treatment with omeprazole, the potential for interactions with drugs metabolised through CYP2C19 should be considered. An interaction is observed between clopidogrel and omeprazole (see Interactions with other medicinal products and other forms of interaction). The clinical relevance of this interaction is uncertain. As a precaution, concomitant use of omeprazole and clopidogrel should be avoided.

Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter (see section "Pharmacodynamic properties").

Severe hypomagnesaemia has been reported in patients treated with proton pump inhibitors (PPIs) like omeprazole for at least three months, and in most cases for a year.

Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously and be overlooked. Hypomagnesaemia may lead to hypocalcaemia and/or hypokalaemia (see section 4.8). In most affected patients, hypomagnesaemia ia (and hypomagnesaemia associated hypocalcaemia and/or hypokalaem) improved after magnesium replacement and discontinuation of the PPI.

For patients expected to be on prolonged treatment or who take PPIs with digoxin or drugs that may cause hypomagnesaemia (e.g. diuretics), healthcare professionals should consider measuring magnesium levels before starting PPI treatment and periodically during treatment.

Proton pump inhibitors, especially if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognized risk factors.Observational studies suggest that proton pump inhibitors may increase the overall risk of fracture by 10–40%. Some of this increase may be due to other risk factors.

Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.

Subacute cutaneous lupus erythematosus (SCLE)

Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping omez. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

Interference with laboratory tests

Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, Omeprazole treatment should be stopped for at least 5 days before CgA measurements (see Pharmacodynamic properties). If CgA and gastrin levels have not returned to reference range after initial measurement, measurements should be repeated 14 days after cessation of proton pump inhibitor treatment.

As in all long-term treatments, especially when exceeding a treatment period of 1 year, patients should be kept under regular surveillance.

Methotrexate and Proton Pump Inhibitors

Use caution when administering high-dose methotrexate to patients receiving proton pump inhibitor (PPI) therapy. Case reports and published population pharmacokinetic studies suggest that concomitant use of some PPIs, such as omeprazole, esomeprazole, and pantoprazole, with methotrexate (primarily at high dose), may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate, possibly leading to methotrexate toxicities. In two of these cases, delayed methotrexate elimination was observed when high-dose methotrexate was co-administered with PPIs, but was not observed when methotrexate was co-administered with ranitidine. However, no formal drug interaction studies of methotrexate with ranitidine have been conducted.

Excipients:

Omez 40 mg IV infusion contains less than 1 mmol sodium (0.999mmole) per dose, essentially 'sodium- free'.

Interaction with other medicinal products and other forms of interaction

Effects of omeprazole on the pharmacokinetics of other active substances

Active substances with pH dependent absorption

The decreased intragastric acidity during treatment with omeprazole might increase or decrease the absorption of active substances with a gastric pH dependent absorption.

Nelfinavir, atazanavir

The plasma levels of nelfinavir and atazanavir are decreased in case of co-administration with omeprazole.

Concomitant administration of omeprazole with nelfinavir is contraindicated (see section "Contraindications"). Co-administration of omeprazole (40 mg once daily) reduced mean nelvinavir exposure by ca. 40% and the mean exposure of the pharmacologically active metabolite M8 was reduced by ca. 75 - 90%. The interaction may also involve CYP2C19 inhibition.

Concomitant administration of omeprazole with atazanavir is not recommended (see Special warnings and precautions for use). Concomitant administration of omeprazole (40 mg once daily) and atazanavir 300 mg/ritonavir 100 mg to healthy volunteers resulted in a 75% decrease of the atazanavir exposure. Increasing the atazanavir dose to 400 mg did not compensate for the impact of omeprazole on atazanavir exposure. The co-administration of omeprazole (20 mg once daily) with atazanavir 400 mg/ritonavir 100 mg to healthy volunteers resulted in a decrease of approximately 30% in the atazanavir exposure as compared to atazanavir 300 mg/ritonavir 100 mg once daily.

Digoxin

Concomitant treatment with omeprazole (20 mg daily) and digoxin in healthy subjects increased the bioavailability of digoxin by 10%. Digoxin toxicity has been rarely reported. However caution should be exercised when omeprazole is given at high doses in elderly patients. Therapeutic drug monitoring of digoxin should be then be reinforced.

Clopidogrel

...dies in healthy subjects have shown a pharmacokinetics (PK/pharmacodynamic (PD) iteraction ...opidogrel (330 mg loading dose/ 75 mg daily maintenance dose) and omeprazole (80 mg p.o. daily) ...g in a decreased exposure to the active metabolite of clopidogrel by an average of 46% and a decreased ...aximum inhibition of (ADP induced) platelet aggregation by an average of 16%.

Inconsistent data on the clinical implications of this PK/PD interaction of omeprazole in terms of major cardiovascular events have been reported from observational and clinical studies. As precaution, concomitant use of omeprazole and clopidogrel should be discouraged (see section "special warnings and precautions for use").

Other active substances
The absorption of posaconazole, erlotinib, ketoconazole and itraconazole is significantly reduced and thus clinical efficacy may be impaired. For posaconazole and erlotinib concomitant use should be avoided.

Active substances metabolised by CYP2C19
Omeprazole is a moderate inhibitor of CYP2C19, the major omeprazole metabolising enzyme. Thus, the metabolism of concomitant active substances also metabolised by CYP2C19, may be decreased and the systemic exposure to these substances increased. Examples of such drugs are R-warfarin and other vitamin K antagonists, cilostazol, diazepam and phenytoin.

Cilostazol

Omeprazole acts as an inhibitor of CYP 2C19. Omeprazole, given in doses of 40 mg daily for one week to 20 healthy subjects in cross-over study, increased Cmax and AUC of cilostazol by 18% and 26% respectively. Cmax and AUC of one of its active metabolites, 3,4-dihydrocilostazol, which has 4-7 times the activity of cilostazol, were increased by 29% and 69% respectively.

Phenytoin
Monitoring phenytoin plasma concentration is recommended during the first two weeks after initiating omeprazole treatment and, if a phenytoin dose adjustment is made, monitoring and a further dose adjustment should occur upon ending omeprazole treatment.

Unknown mechanism

Saquinavir
Concomitant administration of omeprazole with saquinavir/ritonavir resulted in increased plasma levels up to approximately 70% for saquinavir associated with good tolerability in HIV-infected patients.

Tacrolimus
Concomitant administration of omeprazole has been reported to increase the serum levels of tacrolimus. A reinforced monitoring of tacrolimus concentrations as well as renal function (creatinine clearance) should be performed, and dosage of tacrolimus adjusted if needed.

Methotrexate
When given together with proton pump inhibitors, methotrexate levels have been reported to increase in some patients.
In high-dose methotrexate administration a temporary withdrawal of omeprazole may need to be considered.

Effects of other active substances on the pharmacokinetics of omeprazole

Inhibitors of CYP2C19 and/or CYP3A4
Since omeprazole is metabolised by CYP2C19 and CYP3A4, active substances known to inhibit CYP2C19 or CYP3A4 (such as clarithromycin and voriconazole) may lead to increased omeprazole serum levels by decreasing omeprazole's rate of metabolism. Concomitant voriconazole treatment resulted in more than doubling of the omeprazole exposure. As high doses of omeprazole have been well-tolerated adjustment of the omeprazole dose is not generally required. However, dose adjustment should be considered in patients with severe hepatic impairment and if long-term treatment is indicated.

Inducers of CYP2C19 and/or CYP3A4
Active substances known to induce CYP2C19 or CYP3A4 or both (such as rifampicin and St John's wort) may lead to decreased omeprazole serum levels by increasing omeprazole's rate of metabolism.

Fertility, pregnancy and lactation
Pregnancy
Results from three prospective epidemiological studies (more than 1000 exposed outcomes) 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.
Fertility
Animal studies with the racemic omeprazole mixture do not indicate consequences with regard to fertility.

Effects on ability to drive and use machines
Omeprazole is not likely to affect the ability to drive or use machines. Adverse drug reactions such as dizziness and visual disturbances may occur (see Undesirable effects). If affected, patients should not drive or operate machinery.

Undesirable effects
Summary of the side-effect profile
The most common side effects (1-10% of patients) are headache, abdominal pain, constipation, diarrhoea, flatulence and nausea/vomiting.
The following adverse drug reactions have been identified or suspected in the clinical trials programme for omeprazole and post-marketing. None was found to be dose-related. Adverse reactions listed below are classified according to frequency and System Organ Class (SOC). Frequency categories are defined according to the following convention: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000), Not known (cannot be estimated from the available data).

Blood and lymphatic system disorders
Rare: Leukopenia, thrombocytopenia.
Very rare: Agranulocytosis, pancytopenia.

Immune system disorders
Rare: Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock.

Metabolism and nutrition disorders
Rare: Hyponatraemia.
Not known: Hypomagnesaemia; severe hypomagnesaemia may result in hypocalcaemia.
Hypomagnesaemia may also be associated with hypokalaemia.

Psychiatric disorders

...dication of H. pylori with omeprazole and antimicrobials is associated with high rates of healing and long-term remission of peptic ulcers.

Other effects related to acid inhibition
During long-term treatment gastric glandular cysts have been reported in a somewhat increased frequency. These changes are a physiological consequence of pronounced inhibition of acid secretion, are benign and appear to be reversible.

Decreased gastric acidity due to any means including proton pump inhibitors, increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with acid-reducing drugs may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter and, in hospital patients, possibly also Clostridium difficile.

During treatment with antisecretory medicinal products, serum gastrin increases in response to the decreased acid secretion. Also CgA increases due to decreased gastric acidity. The increased CgA level may interfere with investigations for neuroendocrine tumours.
Literature reports indicate that proton pump inhibitor treatment should be stopped at least 5 days before CgA measurements should be repeated 14 days after cessation of omeprazole treatment.
An increased number of ECL cells possibly related to the increased serum gastrin levels, have been observed in some patients (both children and adults) during long term treatment with omeprazole. The findings are considered to be of no clinical significance.
During treatment with antisecretory medicinal products, serum gastrin increases in response to the decreased acid secretion. Also CgA increases due to decreased gastric acidity. The increased CgA level may interfere with investigations for neuroendocrine tumours.
Available published evidence suggests that proton pump inhibitors should be discontinued between 5 days and 2 weeks prior to CgA measurements. This is to allow CgA levels that might be spuriously elevated following PPI treatment to return to reference range.

Pharmacokinetic Properties
Distribution
The apparent volume of distribution in healthy subjects is approximately 0.3 l/kg body weight. Omeprazole is 97% plasma protein bound.

Biotransformation
Omeprazole is completely metabolised by the cytochrome P450 system (CYP). The major part of its metabolism is dependent on the polymorphically expressed CYP2C19, responsible for the formation of hydroxyomeprazole, the major metabolite in plasma. The remaining part is dependent on another specific isoform, CYP3A4, responsible for the formation of omeprazole sulphone. As a consequence of high affinity of omeprazole to CYP2C19, there is a potential for competitive inhibition and metabolic drug-drug interactions with other substrates for CYP2C19. However, due to low affinity to CYP3A4, omeprazole has no potential to inhibit the metabolism of other CYP3A4 substrates. In addition, omeprazole lacks an inhibitory effect on the main CYP enzymes.

Approximately 3% of the Caucasian population and 15–20% of Asian populations lack a functional CYP2C19 enzyme and are called poor metabolisers. In such individuals the metabolism of omeprazole is probably mainly catalysed by CYP3A4. After repeated once-daily administration of 20 mg omeprazole, the mean AUC was 5 to 10 times higher in poor metabolisers than in subjects having a functional CYP2C19 enzyme (extensive metabolisers). Mean peak plasma concentrations were also higher, by 3 to 5 times. These findings have no implications for the posology of omeprazole.

Elimination

Total plasma clearance is about 30-40 l/h after a single dose. The plasma elimination half-life of omeprazole is usually shorter than one hour both after single and repeated once-daily dosing. Omeprazole is completely eliminated from plasma between doses with no tendency for accumulation during once-daily administration. Almost 80% of a dose of omeprazole is excreted as metabolites in the urine, the remainder in the faeces, primarily originating from bile secretion.
The AUC of omeprazole increases with repeated administration. This increase is dose-dependent and results in a non-linear dose-AUC relationship after repeated administration. This time- and dose-dependency is due to a decrease of first pass metabolism and systemic clearance probably caused by an inhibition of the CYP2C19 enzyme by omeprazole and/or its metabolites (e.g. the sulphone).
No metabolite has been found to have any effect on gastric acid secretion.

Special populations
Patients with hepatic impairment: The metabolism of omeprazole in patients with liver dysfunction is impaired, resulting in an increased AUC. Omeprazole has not shown any tendency to accumulate with once-daily dosing.
Patients with renal impairment: The pharmacokinetics of omeprazole, including systemic bioavailability and elimination rate, are unchanged in patients with reduced renal function.
Older people: The metabolism rate of omeprazole is somewhat reduced in elderly subjects (75 - 79 years of age).

Impaired hepatic function

The metabolism of omeprazole in patients with liver dysfunction is impaired, resulting in an increased AUC. Omeprazole has not shown any tendency to accumulate with once-daily dosing.

Impaired renal function
The pharmacokinetics of omeprazole, including systemic bioavailability and elimination rate, are unchanged in patients with reduced renal function.
Older people: The metabolism rate of omeprazole is somewhat reduced in elderly subjects (75 - 79 years of age).

Incompatibilities
This medicinal product should not be mixed with other medicinal products than those mentioned in Method of Administration.

Presentation
Carton box containing 10 ml colorless type I glass vial contains 42.6 mg omeprazole sodium powder for reconstitution covered with stopper made of chlorobutyl rubber cap made of aluminium and a plastic polypropylene lid.

Storage
Keep at a temperature not exceeding 30°C, away from light.
After Dilution: Once diluted the product should be used immediately. The entire contents of each vial (40 mg omeprazole equivalent to 42.6 mg omeprazole sodium) is to be dissolved in approximately 5 ml and then immediately diluted to 100 ml. Sodium chloride 9 mg/ml (0.9%) solution for infusion or glucose 50 mg/ml (5%) solution for infusion must be used. The stability of omeprazole is influenced by the pH of the solution for infusion, which is why no other solvent or quantities should be used for dilution.

Shelf life
2 years
License holder: Pharaonia Pharmaceuticals (Pharo Pharma)
manufacturer name: tenth of Ramadan for pharmaceutical industries and diagnostic agents (Rameda).

Reagents
Dr Marwa
23/10/2022

...mmon: Insomnia.
...are: Agitation, confusion, depression.
Very rare: Aggression, 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, fundic gland polyps (benign).
Rare: Dry mouth, stomatitis, gastrointestinal candidiasis.
Not known: Not known: microscopic colitis.

Hepatobiliary disorders
Uncommon: Increased liver enzymes.
Rare: Hepatitis with or without jaundice.
Very rare: Hepatic failure, encephalopathy in patients with pre-existing liver disease.

Skin and subcutaneous tissue disorders
Uncommon: Dermatitis, pruritus, rash, urticaria.
Rare: Alopecia, photosensitivity.
Very rare: Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis or Lyell syndrome (TEN).
Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS),Subacute cutaneous lupus erythematosus (see section "Special warnings and precautions for use").

Musculoskeletal and connective tissue disorders
Uncommon: Fracture of the hip, wrist or spine (Bone fracture).
Rare: Arthralgia, myalgia. Very rare: Muscular weakness.

Renal and urinary disorders
Rare: Interstitial nephritis.

Reproductive system and breast disorders
Very rare: Gynaecomastia.

General disorders and administration site conditions
Uncommon: Malaise, peripheral oedema.
Rare: Increased sweating.

Irreversible visual impairment has been reported in isolated cases of critically ill patients who have received omeprazole intravenous injection, especially at high doses, but no causal relationship has been established.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via **EPVC mail:** PV.followup@edaegypt.gov.eg

Overdose
There is limited information available on the effects of overdoses of omeprazole in humans. In the literature, doses of up to 560 mg have been described, and occasional reports have been received when single oral doses have reached up to 2,400 mg omeprazole (120 times the usual recommended clinical dose). Nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache have been reported. Also apathy, depression and confusion have been described in single cases.
The symptoms described have been transient, and no serious outcome has been reported. The rate of elimination was unchanged (first order kinetics) with increased doses. Treatment, if needed, is symptomatic.
Intravenous doses of up to 270 mg on a single day and up to 650 mg over a three-day period have been given in clinical trials without any dose-related adverse reactions.

Pharmacological properties
Pharmacodynamic Properties
Pharmacotherapeutic group: Proton pump inhibitors.
Mechanism of action
Omeprazole, a racemic mixture of two enantiomers reduces gastric acid secretion through a highly targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell. It is rapidly acting and provides control through reversible inhibition of gastric acid secretion with once-daily dosing.

Omeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H^+,K^+-ATPase - the acid pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides for highly effective inhibition of both basal acid secretion and stimulated acid secretion, irrespective of stimulus.

Pharmacodynamic effects
All pharmacodynamic effects observed can be explained by the effect of omeprazole on acid secretion.

Effect on gastric acid secretion
Intravenous omeprazole produces a dose dependent inhibition of gastric acid secretion in humans. In order to immediately achieve a similar reduction of intragastric acidity as after repeated dosing with 20 mg orally, a first dose of 40 mg intravenously is recommended. This results in an immediate decrease in intragastric acidity and a mean decrease over 24 hours of approximately 90% for both iv injection and iv infusion.
The inhibition of acid secretion is related to the area under the plasma concentration-time curve (AUC) of omeprazole and not to the actual plasma concentration at a given time.
No tachyphylaxis has been observed during treatment with omeprazole.

Effect on H. pylori
H. pylori is associated with peptic ulcer disease, including duodenal and gastric ulcer disease. H. pylori is a major factor in the development of gastritis. H. pylori together with gastric acid are major factors in the development of peptic ulcer disease. H. pylori is a major factor in the development of atrophic gastritis which is associated with an increased risk of developing gastric cancer.