Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Omisec 40mg/vial Powder for solution for infusion.

2. Qualitative and quantitative composition

Vial contains 40mg of Omeprazole as active substance.
For full list of excipients, see section 6.1

3. Pharmaceutical form

Powder for Solution for intravenous Infusion.

4. Clinical particulars

4.1 Therapeutic indications

Prophylaxis of acid aspiration.
In patients who are unable to take oral therapy for the short-term treatment (up to 5 days) of reflux oesophagitis, duodenal and benign gastric ulcers, including those complicating NSAID therapy e.g. perioperative use.

4.2 Posology and method of administration

Adults only

Prophylaxis of acid aspiration: Omisec 40 mg given as an intravenous infusion to be completed one hour before surgery.
Treatment in patients where oral therapy is inappropriate e.g. in severely ill patients with either reflux oesophagitis, duodenal ulcer or gastric ulcer: Omisec 40 mg given as an intravenous infusion once daily is recommended for up to 5 days.
The i.v. infusion produces an immediate decrease in intragastric acidity and a mean decrease over 24 hours of approximately 90%.
Clinical experience in Zollinger-Ellison syndrome is
limited. Administration
Omisec powder for solution for infusion is for intravenous administration only and must not be given by any other route.
Omisec powder for solution for infusion should only be dissolved in either 100 ml normal saline for infusion or 100 ml 5% dextrose for infusion. No other solutions for i.v. infusion should be used. No other drugs should be mixed with reconstituted Omisec infusion solution.
After reconstitution, from a microbiological point of view, use immediately (i.e. within 3 hours) and any unused portion should be discarded.
The duration of administration should be 20 - 30 minutes.
Use in elderly: Dosage adjustment is not necessary.
Use in children: There is limited experience of use in children.
Impaired renal function: Dose adjustment is not required in patients with impaired renal function.
Impaired hepatic function: As half-life is increased in patients with impaired

hepatic function, the dose requires adjustment and a daily dose of 10 – 20 mg may be sufficient.

4.3 Contraindications

Known hypersensitivity to omeprazole or to any of the other constituents of the formulation. Omeprazole, like other proton pump inhibitors, should not be administered with atazanavir.

4.4 Special warnings and precautions for use

When gastric ulcer is suspected the possibility of malignancy should be excluded before treatment with Ominsec is instituted, as treatment may alleviate symptoms and delay diagnosis.

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 a slightly increased risk of gastrointestinal infections, such as *Salmonella* and *Campylobacter*.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the decreased intragastric acidity, the absorption of ketoconazole or itraconazole may be reduced during omeprazole therapy as it is during treatment with other acid secretion inhibitors.

As omeprazole is metabolized in the liver through cytochrome P450, it can prolong the elimination of diazepam, phenytoin and warfarin. Monitoring of patients receiving phenytoin or warfarin is recommended and a reduction of phenytoin or warfarin dose may be necessary when omeprazole is added to treatment. However, concomitant treatment with omeprazole 20 mg orally daily did not change the blood concentration of phenytoin in patients on continuous treatment with phenytoin. Similarly, concomitant treatment with omeprazole 20 mg orally daily did not change coagulation time in patients on continuous treatment with warfarin.

Plasma concentrations of omeprazole and clarithromycin are increased during concomitant oral administration. There is no interaction with metronidazole or amoxicillin. These antimicrobials are used together with omeprazole for eradication of *Helicobacter pylori*.

There is no evidence of an interaction with phenacetin, theophylline, caffeine, propranolol, metoprolol, cyclosporine, lidocaine, quinidine, estradiol, or antacids when omeprazole is given orally. The absorption of omeprazole given orally is not affected by alcohol or food.

There is no evidence of an interaction with piroxicam, diclofenac or naproxen, this is considered useful when patients are required to continue these treatments.

Simultaneous treatment with omeprazole and digoxin in healthy people led to a 10% increase in the bioavailability of digoxin as a consequence of the increased intragastric pH.Interaction with other drugs also metabolized via

cytochrome P450 system cannot be excluded. Co-administration of omeprazole (40 mg once daily) with atazanavir 300 mg/ritonavir 100 mg to healthy people will result in a substantial reduction in atazanavir exposure (approximately 75% decrease in AUC, Cmax, and Cmin). Increasing the atazanavir dose to 400 mg did not compensate for the impact of omeprazole on atazanavir exposure. Proton pump inhibitors including omeprazole should not be co-administered with atazanavir .

Concomitant administration of omeprazole and tacrolimus may increase the serum levels of tacrolimus

4.6 pregnancy and lactation

Use in pregnancy: no evidence of adverse events of omeprazole on pregnancy or on the health of the fetus/newborn child. Omisec can be used during pregnancy.

Use in lactation: Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used

4.7 Effects on ability to drive and use machines

No effects are anticipated

4.8 Undesirable effects

Omeprazole is well tolerated and adverse reactions have generally been mild and reversible. The following have been reported as adverse events reported from routine use, but in many cases a relationship to treatment with omeprazole has not been established. The following definitions of frequencies are used: Common > 1/100; Uncommon > 1/1000 and < 1/100; Rare < 1/1000.

Common

Central and peripheral nervous system: Headache.

Gastrointestinal: Diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence. Uncommon

C*entral and peripheral nervous system:* Dizziness, paresthesia, light-headedness, feeling faint, somnolence, insomnia and vertigo.

Hepatic: Increased liver enzymes. *Skin:* Rash and/or pruritus, urticaria. *Other:* Malaise.

Rare

Central and peripheral nervous system: Reversible mental confusion, agitation, aggression, depression and hallucinations, predominantly in severely ill patients.

Endocrine: Gynaecomastia.

Gastrointestinal: Dry mouth, stomatitis and gastrointestinal candidiasis.

Haematological: Leukopenia, thrombocytopenia, agranulocytosis and pancytopenia. *Hepatic:* Encephalopathy in patients with pre-existing

severe liver disease; hepatitis with or without jaundice, hepatic failure, increased liver enzymes.
Musculoskeletal: Arthritic and myalgic symptoms and muscular weakness.
Reproductive system: Impotence.
Skin: Photosensitivity, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, alopecia.
Other: Hypersensitivity reactions (e.g. angioedema, fever, bronchospasm, interstitial nephritis and anaphylactic shock), increased sweating, peripheral oedema, blurred vision, taste disturbance and hyponatraemia.

Isolated cases of irreversible visual impairment have been reported in critically ill patients who have received Omisec intravenous injection, particularly at high doses, however no causal relationship has been established.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via the relevant national regulatory authority pharmacovigilance.

4.9 Overdose
It has been reported that intravenous administration of omeprazole in doses up to 270 mg on a single day and up to 650 mg over a three-day period has not resulted in any dose-related adverse reactions.

5. Pharmacological properties
5.1 Pharmacodynamics properties
Omeprazole reduces gastric acid secretion through a unique mechanism of action. It is a specific inhibitor of the gastric proton pump in the parietal cell. It is rapidly acting and produces reversible control of gastric acid secretion with once daily dosing.
Intravenous administration of omeprazole results in an immediate reduction of intragastric acidity and a mean decrease over 24 hours of approximately 90% in patients with duodenal ulcer disease.
A higher dose of 60 mg i.v. twice daily has been used in patients with Zollinger-Ellison syndrome.
Site and mechanism of action
Omeprazole is a weak base and is concentrated and converted to the active form in the acid environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H+, K+,-ATPase–the proton pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides effective inhibition of both basal acid secretion and stimulated acid secretion irrespective of the stimulus.
All pharmacodynamic effects observed are explained by the effect of omeprazole on acid secretion. No tachyphylaxis has been observed during

treatment with omeprazole.

5.2 Pharmacokinetic properties

Distribution

The apparent volume of distribution in healthy people and for patients with renal insufficiency is approximately 0.3 L/kg. In the elderly and in patients with hepatic insufficiency, the volume of distribution is slightly decreased. The plasma protein binding of omeprazole is about 95%.

Metabolism and excretion

The average half-life of the terminal phase of the plasma concentration-time curve following i.v. administration of omeprazole is approximately 40 minutes; the total plasma clearance is 0.3 to
0.6 L/min. There is no change in half-life during treatment.

Omeprazole is completely metabolised by the cytochrome P450 system, mainly in the liver. The major part of its metabolism is dependent on the polymorphically expressed, specific isoform CYP2C19 (S-mephenytoin hydroxylase), responsible for the formation of hydroxyomeprazole, the major metabolite in plasma.

No metabolite has been found to have any effect on gastric acid secretion. Almost 80% of an intravenously given dose is excreted as metabolites in the urine, and the remainder is found in the faeces, primarily originating from biliary secretion.

Elimination of omeprazole is unchanged in patients with reduced renal function. The elimination half-life is increased in patients with impaired liver function, but omeprazole has not shown any accumulation with once daily oral dosing.

5.3 Preclinical safety data

N.A.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Hydroxide, Edetate Disodium and Water for Injection.

6.2 Incompatibilities

N.A.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 30°C & protect from light

6.5 Nature and contents of container
Clear Tubular Glass Vial 6R with Rubber Stopper 20mm Lyo.

6.6 Special precautions for disposal and other handling
N.A.

7. Marketing authorization holder
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8. **Marketing Authorization Number**

H2026/CTD7983/15240

9. Date of first authorization/renewal of the authorization

2026, March 30

10. Date of revision of the text

2026, March 30