Neege® Tablets

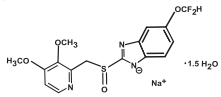
(Pantoprazole Sodium)

COMPOSITION:

Neege® 20mg tablets
Each delayed release tablet contains:
Pantoprazole Sodium Sesquihydrate USP
equivalent to Pantoprazole 20mg

Neege® 40mg tablets
Each delayed release tablet contains:
Pantoprazole Sodium Sesquihydrate USP
equivalent to Pantoprazole 40mg

DESCRIPTION:
The active ingredient in pantoprazole sodium delayed-release tablets is a substituted benzimidazole, sodium 5-(difluoromethoxy)-2-[[(3,4-dimethoxy-2-pyridinyl)methyl] sulfinyl]-1*H*-benzimidazole sesquihydrate, a compound that inhibits gastric acid secretion. Its empirical formula is $C_{16}H_{14}F_2N_3NaO_4S$ x 1.5 H_2O, with a molecular weight of 432.4



Pantoprazole sodium sesquihydrate is a white to off-white crystalline powder and is racemic. Pantoprazole sodium has weakly basic and acidic properties. Pantoprazole sodium sesquihydrate is freely soluble in water, very slightly soluble in phosphate buffer at pH 7.4, and practically insoluble in n-hexane

The stability of the compound in aqueous solution is pH-dependent. The rate of degradation increases with decreasing pH. At ambient temperature, the degradation half-life is approximately 2.8 hours at pH 5 and approximately 220 hours at pH 7.8

Each pantoprazole sodium delayed-release tablet contains 22.56mg and 45.1mg of pantoprazole sodium sesquihydrate (equivalent to 20mg and 40mg pantoprazole sodium respectively)

CLINICAL PHARMACOLOGY:
Mechanism of Action: Pantoprazole sodium is a proton pump inhibitor (PPI) that suppresses the final step in gastric acid production by covalently binding to the (H^+, K^+)-ATPase enzyme system at the secretory surface of the gastric parietal cell. This effect leads to inhibition of both basal and stimulated gastric acid secretion, irrespective of the stimulus. The binding to the (H^+, K^+)-ATPase results in a duration of antisecretory effect that persists longer than 24 hours for all doses tested (20mg to 120mg)

Pharmacodynamics
Antisecretory activity: Under maximal acid stimulatory conditions using pentagastrin, a dose-dependent decrease in gastric acid output occurs after a single dose of oral (20-80mg). Pantoprazole sodium given once daily results in increasing inhibition of gastric acid secretion. Following the initial oral dose of 40mg pantoprazole sodium, a 51% mean inhibition was achieved by 2.5 hours. With once-a-day dosing for 7 days, the mean inhibition was increased to 85%. Pantoprazole sodium suppressed acid secretion in excess of 95% in half of the subjects. Acid secretion had returned to normal within a week after the last dose of pantoprazole sodium; there was no evidence of rebound hypersecretion

Pharmacokinetics: Pantoprazole sodium does not accumulate, and its pharmacokinetics are unaltered with multiple daily dosing. Following oral or intravenous administration, the serum concentration of pantoprazole sodium declines biexponentially, with a terminal elimination half-life of approximately one hour

In extensive metabolizers with normal liver function receiving an oral dose of the enteric-coated 40mg pantoprazole sodium tablet, the peak concentration (C_{max}) is 2.5µg/ml; the time to reach the peak concentration (T_{max}) is 2.5 h, and the mean total area under the plasma concentration versus time curve (AUC) is 4.8µg h/ml (Range: 1.4 to 13.3µg h/ml)

Absorption: Pantoprazole is rapidly absorbed and peak plasma pantoprazole concentrations are achieved about 2 to 2.5 hours after an oral dose. The oral bioavailability is about 77% with the enteric coated tablet formulation, and does not vary after single or multiple doses

Administration of pantoprazole sodium delayed-release tablets with food may delay its absorption up to 2 hours or longer; however, the Cmax and the extent of pantoprazole absorption (AUC) are not altered. Thus, pantoprazole delayed-release tablets may be taken without regard to timing of meals

Distribution: The apparent volume of distribution of pantoprazole sodium is approximately 11.0 - 23.6L, distributing mainly in extracellular fluid. The serum protein binding of pantoprazole sodium is about 98%, primarily to albumin

Metabolism: Pantoprazole sodium is extensively metabolized in the liver through the cytochrome P450 (CYP) system. Pantoprazole sodium metabolism is independent of the route of administration (intravenous or oral)

Elimination: After a single oral dose, approximately 71% of the dose was excreted in the urine, with 18% excreted in the feces through biliary excretion. There was no renal excretion of unchanged pantoprazole sodium

Geriatric: Only slight to moderate increase in pantoprazole sodium AUC (43%) and C_{max} (26%) were found in elderly volunteers (64 to 76 years of age) after repeated oral administration

Paediatric: The pharmacokinetics of pantoprazole delayed-release tablets was evaluated in children ages 6 through 16 years with a clinical diagnosis of GERD. The PK parameters following a single oral dose of 20mg or 40mg of pantoprazole delayed release tablets in children ages 6 through 16 years were highly variable (% CV ranges 40 to 80%). The geometric mean AUC estimated from population PK analysis after a 40mg pantoprazole delayed release tablets in paediatric patients was about 39% and 10% higher respectively in 6 to 11 and 12 to 16 years - old children, compared to that of adults

Renal Impairment: No dosage adjustment is necessary in patient with renal impairment or in patient undergoing hemodialysis

Hepatic Impairment: No dosage adjustment is needed in patient with mild to severe hepatic impairment. Doses higher than 40mg/day have not been studied in hepatically impaired patients

Drug-Drug Interactions: Pantoprazole sodium is metabolized mainly by CYP2C19 and to minor extents by CYPs 3A4, 2D6, and 2C9, *in vivo* drug-drug interaction studies with CYP2C19 substrates (diazepam [also a CYP3A4 substrate] and phenytoin [also a CYP3A4 inducer]), nifedipine, midazolam,and clarithromycin (CYP3A4 substrates), metoprolol (a CYP2D6 substrate)), diclofenac, naproxen, piroxicam (CYP2C9 substrates) and theophylline (a CYP1A2 substrate) in healthy subjects, the pharmacokinetics of pantoprazole sodium were not significantly altered

Based on studies evaluating possible interactions of pantoprazole sodium with other drugs, no dosage adjustment is needed with concomitant use of the following: Theophylline, cisapride, antipyrine, caffeine, carbamazepine, diazepam (and its active metabolite, desmethyldiazepam), diclofenac, naproxen, piroxicam, digoxin, ethanol, glyburide, an oral contraceptive (levonorgestrel/ethinyl estradiol), metoprolol, nifedipine, phenytoin, warfarin, midazolam, clarithromycin, metronidazole, or amoxicillin

INDICATION AND USAGE:
Pantoprazole sodium delayed-release tablets are indicated for:
- Peptic ulcer
- For the eradication of Helicobacter pylori combined with two antibacterials
- Short-term treatment of erosive esophagitis associated with gastroesophageal reflux disease (GERD)
- Maintenance of healing of erosive esophagitis
- Pathological hypersecretory condition including Zollinger-Ellison Syndrome

CONTRAINDICATIONS:
Pantoprazole sodium delayed-release tablets are contraindicated in patients with known hypersensitivity to any component of the formulation

WARNING AND PRECAUTIONS:
Concurrent Gastric Malignancy: Symptomatic response to therapy with pantoprazole sodium does not preclude the presence of gastric malignancy
Atrophic Gastritis
Cyanocobalamin (Vitamin B-12) Deficiency
Tumorigenicity: Due to chronic nature of GERD, there may be a potential for prolonged administration of pantoprazole sodium. In long-term rodent studies, pantoprazole sodium was carcinogenic and caused rare types of gastrointestinal tumors. The relevance of these findings to tumor development in humans is unknown

ADVERSE REACTION:
Adults: Adverse reactions reported in patients with GERD at a frequency of > 2%: Headache, diarrhoea, nausea, abdominal pain, vomiting, flatulence, dizziness and arthralgia
Additional adverse reactions that were reported for pantoprazole sodium in clinical trials with a frequency of ≤ 2% are listed below by body system:

- **Body as a whole**: Allergic reaction, pyrexia, photosensitivity reaction, facial edema
- **Gastrointestinal**: Constipation, dry mouth, hepatitis
- **Hematologic**: Leukopenia, thrombocytopenia
- **Metabolic / Nutritional**: Elevated CK (creatine kinase), generalized edema, elevated triglycerides, liver enzymes elevated
- **Musculoskeletal**: Myalgia
- **Nervous**: Depression, vertigo
- **Skin and Appendages**: Urticaria, rash, pruritus
- **Special Senses**: Blurred vision

Paediatric Patients: All adult adverse reactions to pantoprazole sodium are considered relevant to paediatric patients

Zollinger-Ellison Syndrome
In clinical studies of Zollinger-Ellison Syndrome, adverse reactions reported in 35 patients taking pantoprazole sodium 80mg/day to 240mg/day for up to 2 years were similar to those reported in adult patients with GERD

USE IN SPECIFIC POPULATIONS:
Pregnancy
Pregnancy Category B
Nursing Mothers
Pantoprazole sodium excretion in human milk has been detected in a study of a single nursing mother after a single 40mg oral dose, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother
Paediatric Use
The safety and effectiveness of pantoprazole sodium for short-term treatment (up to eight weeks) of erosive esophagitis (EE) associated with GERD have been established in paediatric patients 1 year through 16 years of age. Effectiveness for EE has not been demonstrated in patients less than 1 year of age. Therefore, pantoprazole sodium is indicated for the short-term treatment of EE associated with GERD for patients 5 years and older
Geriatric Use
Erosive esophagitis healing rates in elderly patients(≥ 65 years old) treated with pantoprazole sodium were similar to those found in patients under the age of 65
Gender
Erosive esophagitis healing rates treated with pantoprazole sodium delayed-release tablets in US clinical trials were similar to those found in men. In the 122 women treated long-term with pantoprazole sodium 40mg or 20mg, healing was maintained at a rate similar to that in men. The incidence rates of adverse reactions were also similar for men and women
Patients with Hepatic Impairment
Doses higher than 40mg/day have not been studied in patients with hepatic impairment

OVERDOSAGE:
Experience in patients taking very high doses of pantoprazole sodium (> 240mg) is limited. Spontaneous post-marketing reports of overdose are generally within the known safety profile of pantoprazole sodium

Pantoprazole sodium is not removed by hemodialysis. In case of over dosage, treatment should be symptomatic and supportive

DOSAGE AND ADMINISTRATION:

Peptic Ulcer Disease		
Duodenal ulceration		
Adults	40mg	Once daily 2 to 4 weeks
Benign gastric ulceration		
Adults	40mg	Once daily 4 to 8 weeks

Eradication of Helicobacter pylori (1 week triple therapy regimen)
- Pantoprazole 40mg twice daily + Clarithromycin 500mg twice daily + Amoxicillin 1g twice daily
- Pantoprazole 40mg twice daily + Clarithromycin 500mg twice daily + Metronidazole 400mg twice daily

Short-term Treatment of Erosive Esophagitis Associated with GERD		
Adults	40mg	Once daily for up to 8 weeks*
Children (5 years and older)		
≥ 15Kg to < 40Kg	20mg	Once daily for up to 8 weeks
≥ 40Kg	40mg	
Maintenance of Healing of Erosive Esophagitis		
Adults	40mg	Once daily for up to 8 weeks
Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome		
Adults	40mg	Twice daily **

* For adult patients who have not healed after 8 weeks of treatment, an additional 8-week course of pantoprazole sodium may be considered
** Dosage regimens should be adjusted to individual patient needs and should continue for as long as clinically indicated. Doses up to 240mg daily have been administered

OR
As directed by the physician

STABILITY:
See expiry on the pack

PRESENTATIONS:
Neege® 20mg tablets in a pack of 14's
Neege® 40mg tablets in a pack of 14's

INSTRUCTIONS:
To be swallowed whole with water
Keep out of reach of children
Avoid exposure to heat, light and humidity
Store between 15 to 30°C
Improper storage may deteriorate the medicine

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

نیج ٹیبلٹ

(پینٹوپرازول سوڈیم)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
ہدایات: ثابت ٹیبلٹ چبائے بغیر پانی سے نگل لیں
بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

P001768/S R.N-05/HA/12/15

220 mm

71 mm

Neege®

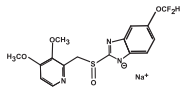
40mg Injection

(Pantoprazole Sodium)

COMPOSITION:
Each vial contains:
Pantoprazole Sodium USP
equivalent to Pantoprazole 40mg
(Suitably buffered)

DESCRIPTION:

The active ingredient in **Neege®** I.V. (Pantoprazole sodium) for injection is a substituted benzimidazole, sodium 5-(difluoromethoxy)-2-[(3,4-dimethoxy-2-pyridinyl)methyl] sulfinyl]-1H-benzimidazole, a compound that inhibits gastric acid secretion. Its empirical formula is $C_{16}H_{14}F_2N_3NaO_4S$, with a molecular weight of 405.4



Pantoprazole sodium is a white to off-white crystalline powder and is racemic. Pantoprazole has weakly basic and acidic properties. Pantoprazole sodium is freely soluble in water, very slightly soluble in phosphate buffer at pH 7.4, and practically insoluble in n-hexane. The stability of the compound in aqueous solution is pH-dependent. The rate of degradation increases with decreasing pH

CLINICAL PHARMACOLOGY:

Mechanism of Action: Pantoprazole is a proton pump inhibitor (PPI) that suppresses the final step in gastric acid production by covalently binding to the (H^+, K^+)-ATPase enzyme system at the secretory surface of the gastric parietal cell. This effect leads to inhibition of both basal and stimulated gastric acid secretion irrespective of the stimulus. The binding to the (H^+, K^+)-ATPase results in a duration of antisecretory effect that persists longer than 24 hours for all doses tested

Pharmacokinetics: Pantoprazole peak serum concentration (C_{max}) and area under the serum concentration-time curve (AUC) increase in a manner proportional to intravenous doses from 10mg to 80mg. Pantoprazole does not accumulate and its pharmacokinetics are unaltered with multiple daily dosing. Following the administration of pantoprazole I.V. for injection, the serum concentration of pantoprazole declines biexponentially with a terminal elimination half-life of approximately one hour

Distribution: The apparent volume of distribution of pantoprazole is approximately 11.0-23.6 L, distributing mainly in extracellular fluid. The serum protein binding of pantoprazole is about 98%, primarily to albumin

Metabolism: Pantoprazole is extensively metabolized in the liver through the cytochrome P450 (CYP) system. Pantoprazole metabolism is independent of the route of administration (intravenous or oral)

Elimination: After administration of a single intravenous dose of ^{14}C-labeled pantoprazole to healthy, normal metabolizer subjects, approximately 71% of the dose was excreted in the urine with 18% excreted in the feces through biliary excretion. There was no renal excretion of unchanged pantoprazole

SPECIAL POPULATIONS:

Geriatric: After repeated I.V. administration in elderly subjects (65 to 76 years of age), pantoprazole AUC and elimination half-life values were similar to those observed in younger subjects. No dosage adjustment is recommended based on age

Paediatric: The pharmacokinetics of pantoprazole have not been investigated in patients <18 years of age

Renal Impairment: No dosage adjustment is necessary in patients with renal impairment or in patients undergoing hemodialysis

Hepatic Impairment: No dosage adjustment is needed in patients with mild to severe hepatic impairment. Doses higher than 40mg/day have not been studied in hepatically-impaired patients

Therapeutic Indications

- Gastroesophageal reflux disease associated with erosive esophagitis
- Pathological hypersecretion associated with Zollinger- Ellison Syndrome

INDICATIONS AND USAGE:

Treatment of Gastroesophageal Reflux Disease Associated With a History of Erosive Esophagitis: Pantoprazole sodium I.V. for injection is indicated for short-term treatment (7 to 10 days) of patients with gastroesophageal reflux disease (GERD) and a history of erosive esophagitis

Pathological Hypersecretion Associated with Zollinger-Ellison Syndrome: Pantoprazole sodium I.V. for injection is indicated for the treatment of pathological hypersecretory conditions associated with Zollinger-Ellison Syndrome or other neoplastic conditions

CONTRAINDICATIONS:

Neege® I.V. for injection is contraindicated in patients with known hypersensitivity to the formulation

PRECAUTIONS:

General: Immediate hypersensitivity reactions: Anaphylaxis has been reported with use of intravenous pantoprazole. This may require emergency medical treatment

Injection site reactions: Thrombophlebitis was associated with the administration of intravenous pantoprazole. Hepatic effects: Mild, transient transaminase elevations have been observed in clinical studies. The clinical significance of this finding in a large population of subjects administered intravenous pantoprazole is unknown

Symptomatic response to therapy with pantoprazole does not preclude the presence of gastric malignancy

DRUG INTERACTIONS:

Pantoprazole is metabolized through the cytochrome P450 system, primarily the CYP2C19 and CYP3A4 isozymes, and subsequently undergoes Phase II conjugation

Based on studies evaluating possible interactions of pantoprazole with other drugs, no dosage adjustment is needed with concomitant use of the following: theophylline, cisapride, antipyrine, caffeine, carbamazepine, diazepam (and its active metabolite, desmethyldiazepam), diclofenac, naproxen, piroxicam, digoxin, ethanol, glyburide, an oral contraceptive (levonorgestrel/ethinyl estradiol), metoprolol, nifedipine, phenytoin, warfarin (see below), midazolam, clarithromycin, metronidazole, or amoxicillin. Clinically relevant interactions of pantoprazole with other drugs with the same metabolic pathways are not expected. Therefore, when co-administered with pantoprazole, adjustment of the dosage of pantoprazole or of such drugs may not be necessary. There was also no interaction with concomitantly administered antacids

Because of profound and long lasting inhibition of gastric acid secretion, pantoprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g., ketoconazole, ampicillin esters, and iron salts)

PREGNANCY:

Teratogenic Effects
Pregnancy Category B

Nursing Mothers: Pantoprazole excretion in human milk has been detected in a study of a single nursing mother after a single 40mg oral dose. The clinical relevance of this finding is not known

Paediatric Use: Safety and effectiveness in paediatric patients have not been established

Use in Women: The incidence rates of adverse events were also similar between men and women

Use in Elderly: The incidence rates of adverse events and laboratory abnormalities in patients aged 65 years and older were similar to those associated with patients younger than 65 years of age

Laboratory Tests: There have been reports of false-positive urine screening tests for tetrahydrocannabinol (THC) in patients receiving most proton pump inhibitors, including pantoprazole. An alternative confirmatory method should be considered to verify positive results

ADVERSE REACTIONS:

Safety Experience with Intravenous Pantoprazole

Intravenous pantoprazole has been studied in clinical trials in several populations including patients with GERD and a history of erosive esophagitis, patients with Zollinger-Ellison Syndrome, patients involved in clinical trials for other disorders which may respond to proton pump inhibitor therapy, and healthy subjects. Adverse experiences occurring in >1% of patients treated with intravenous pantoprazole (n=836) in domestic or international clinical trials are shown below by body system. In most instances, the relationship to pantoprazole was unclear

Body as a whole: Abdominal pain, headache, injection site reaction (including thrombophlebitis and abscess)
Digestive system: Constipation, dyspepsia, nausea, diarrhea
Nervous system: Insomnia, dizziness
Respiratory system: Rhinitis

OVERDOSAGE:

Pantoprazole is not removed by hemodialysis. In case of overdose, treatment should be symptomatic and supportive. The symptoms of acute toxicity were hypoactivity, ataxia, hunched sitting, limb-splay, lateral position, segregation, absence of ear reflex, and tremor

DOSAGE AND ADMINISTRATION:

Neege® I.V. for injection may be administered intravenously through a dedicated line or through a Y-site. The intravenous line should be flushed before and after administration of **Neege®** I.V. for injection with either 5% dextrose injection, USP, 0.9% sodium chloride injection, USP, or lactated ringer's injection, USP. When administered through a Y-site, pantoprazole sodium I.V. for injection is compatible with the following solutions: 5% dextrose injection, USP, 0.9% sodium chloride injection, USP, or lactated ringer's injection, USP

Midazolam HCl has been shown to be incompatible with Y-site administration of pantoprazole sodium I.V. for injection. Pantoprazole sodium I.V. for injection may not be compatible with products containing zinc. When **Neege®** I.V. for injection is administered through a Y-site, immediately stop use if precipitation or discoloration occurs

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to and during administration whenever solution and container permit

Treatment of Gastroesophageal Reflux Disease Associated With a History of Erosive Esophagitis: The recommended adult dose is 40mg pantoprazole given once daily by intravenous infusion for 7 to 10 days. Safety and efficacy of pantoprazole sodium I.V. for injection as a treatment of patients with GERD and a history of erosive esophagitis for more than 10 days have not been demonstrated

For I.V. Infusion: Neege® I.V. for injection should be reconstituted with 10ml of 0.9% sodium chloride injection, USP, and further diluted (admixed) with 100ml of 5% dextrose injection, USP, 0.9% sodium chloride injection, USP, or lactated ringer's injection, USP, to a final concentration of approximately 0.4 mg/ml. The reconstituted solution may be stored for up to 6 hours at room temperature prior to further dilution. The admixed solution may be stored at room temperature and must be used within 24 hours from the time of initial reconstitution. Both the reconstituted solution and the admixed solution do not need to be protected from light

Neege® I.V. for injection admixtures should be administered intravenously over a period of approximately 15 minutes at a rate of approximately 7ml/min

For I.V. Injection: Neege® I.V. for injection should be reconstituted with 10ml of 0.9% Sodium Chloride Injection, USP, to a final concentration of approximately 4mg/ml. The reconstituted solution may be stored for up to 24 hours at room temperature prior to intravenous infusion and does not need to be protected from light. **Neege®** I.V. for injection should be administered intravenously over a period of at least 2 minutes

Pathological Hypersecretion Associated with Zollinger-Ellison Syndrome: The dosage of **Neege®** I.V. for injection in patients with pathological hypersecretory conditions associated with Zollinger-Ellison Syndrome or other neoplastic conditions varies with individual patients. The recommended adult dosage is 80mg q12h. The frequency of dosing can be adjusted to individual patient needs based on acid output measurements. In those patients who need a higher dosage, 80mg q8h is expected to maintain acid output below 10mEq/h. Daily doses higher than 240mg or administered for more than 6 days have not been studied. Transition from oral to I.V. and from I.V. to oral formulations of gastric acid inhibitors should be performed in such a manner to ensure continuity of effect of suppression of acid secretion. Patients with Zollinger-Ellison Syndrome may be vulnerable to serious clinical complications of increased acid production even after a short period of loss of effective inhibition

For I.V. Infusion: Each vial of **Neege®** I.V. for injection should be reconstituted with 10ml of 0.9% sodium chloride injection, USP. The contents of the two vials should be combined and further diluted (admixed) with 80ml of 5% dextrose injection, USP, 0.9% sodium chloride injection, USP, or lactated ringer's injection, USP, to a total volume of 100ml with a final concentration of approximately 0.8mg/ml. The reconstituted solution may be stored for up to 6 hours at room temperature prior to further dilution. The admixed solution may be stored at room temperature and must be used within 24 hours from the time of initial reconstitution. Both the reconstituted solution and the admixed solution do not need to be protected from light

Neege® I.V. for injection should be administered intravenously over a period of approximately 15 minutes at a rate of approximately 7ml/min

For I.V. Injection: Neege® I.V. for injection should be reconstituted with 10ml of 0.9% sodium chloride injection, USP, per vial to a final concentration of approximately 4mg/ml. The reconstituted solution may be stored for up to 24 hours at room temperature prior to intravenous infusion and does not need to be protected from light. The total volume from both vials should be administered intravenously over a period of at least 2 minutes

OR
As directed by the physician

DIRECTION FOR RECONSTITUTION:

For I.V. Injection: The freeze-dried powder should be reconstituted with 10ml of 0.9% sodium chloride (provided with the pack)

For I.V. Infusion: Dissolve the contents of **Neege®** 40mg vial with 10ml of solvent (0.9% of sodium chloride solution for injection or 5% glucose) and further dilute the resulting solution to a final volume of 100ml

After preparation, the solution must be used within 12 hours. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C

The appearance of the product after reconstitution is clear yellowish solution

STABILITY:
See expiry on pack

PRESENTATION:

Neege® (Pantoprazole) 40mg injection lyophilized powder for injection is available as 1 vial plus 10ml 0.9% w/v sodium chloride injection

INSTRUCTIONS:
Keep out of reach of children
Avoid exposure to heat, light and humidity
Store between 15 to 30°C
Improper storage may deteriorate the medicine
The reconstituted solution should be administered with in 24 hrs. after preparation

نیِج ۴۰ ملی گرام انجکشن
(پینٹوپرازول سوڈیم)
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
ہدایات: بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

P000856/S R.N-03/HA/12/15

220 mm

71 mm