Perinem
Injection (IV)

Composition : Doripenem INN 500mg as Doripenem Monohydrate sterile powder for IV injection.

Indications : Doripenem is indicated in the treatment of the following infections. **Complicated Intra-Abdominal Infections :** Complicated intra-abdominal infections caused by *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Bacteroides caccae, Bacteroides fragilis, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Streptococcus intermedius, Streptococcus constellatus* and *Peptostreptococcus micros.* **Complicated Urinary Tract Infections, Including Pyelonephritis :** Complicated urinary tract infections, including pyelonephritis caused by *Escherichia coli* including cases with concurrent bacteremia, *Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa,* and *Acinetobacter baumannii.*

Dosage and administration : The recommended dosage is 500mg administered every 8 hours by intravenous infusion over one hour in patient's >18 years of age.

Infection	Dosage	Frequency	Infusion Time (hours)	Duration
Complicated intra-abdominal infection	500mg	every 8 hours	1	5-14 days *
Complicated UTI,including pyelonephritis	500mg	every 8 hours	1	10 days *

Dosage of Doripenem in patients with renal impairment :

Estimated CrCl (ml/min)	Recommended Dosage Regimen of Doripenem
> 50	No dosage adjustment necessary
⩾ 30 to ⩽ 50	250mg* administered intravenously (over 1 hour) every 8 hours
> 10 to < 30	250mg* administered intravenously (over 1 hour) every 12 hours

* Duration includes a possible switch to an appropriate oral therapy, after at least 3 days of parenteral therapy, once clinical improvement has been demonstrated. Or, as directed by the registered physician.

Preparation of Solution : (Preparation of 500mg) Constitute the 500 mg vial with 10 ml of sterile water for injection or 0.9% sodium chloride injection (normal saline) and gently shake to form a suspension. The resultant concentration is approximately 50 mg/ml. **Caution:** The constituted suspension is not for direct injection. Withdraw the suspension using a syringe with a 21 gauge needle and add it to an infusion bag containing 100 ml of normal saline or 5% dextrose; gently shake until clear. The final infusion solution concentration is approximately 4.5mg/ml.

Contraindications : It is contraindicated in patients with known hypersensitivity to Doripenem or any other components of this drug or patients who have demonstrated anaphylactic reactions to beta-lactams.

Use in pregnancy and lactation : Pregnancy category B. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. It is not known whether this drug is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when Doripenem is administered to a nursing woman.

Side effects : The side effects are headache, diarrhea, nausea, phlebitis, rash, vulvomycotic infection.

Precautions : Serious and occasionally fatal hypersensitivity (anaphylactic) and serious skin reactions have been reported in patients receiving beta-lactam antibiotics. Before therapy with Doripenem is instituted, careful inquiry should be made concerning a previous history of hypersensitivity reactions to other active substances in this class or to beta-lactam antibiotics.

Drug interactions : Co-administration of Doripenem with valproic acid causes the serum concentrations of valproic acid to fall below the therapeutic range, increasing the risk for breakthrough seizures. Probenecid interferes with the active tubular secretion of doripenem, resulting in increased plasma concentrations of doripenem. Co-administration of probenecid with Doripenem is not recommended.

Packing : Perinem (IV) Injection : 1 Combipack