Iventi™ 400 IV

Moxifloxacin 0.16% w/v

COMPOSITION

Iventi™ 400 IV : 250 ml sterile solution contains Moxifloxacin 400 mg as Moxifloxacin Hydrochloride BP.

PHARMACOLOGY

Moxifloxacin is a broad spectrum fluoroquinolon which has activity against a wide range of Gram-positive and Gram-negative microorganisms. The bactericidal action of moxifloxacin results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV required for bacterial DNA replication, transcription, repair, and recombination.

There is no known cross-resistance between moxifloxacin and other classes of antimicrobials.

INDICATION

Moxifloxacin infusion is indicated for treating following infections in adults ≥ 18 years of age caused by designated, susceptible bacteria.

- Acute Bacterial Sinusitis
- Acute Bacterial Exacerbation of Chronic Bronchitis
- Community Acquired Pneumonia
- Skin and Skin Structure Infections: Uncomplicated and Complicated
- Complicated Intra-Abdominal Infections

DOSAGE AND ADMINISTRATION

The dose of Moxifloxacin is 400 mg (orally or as an intravenous infusion) once daily. The duration of therapy depends on the type of infection as described in following table:

Type of Infection	Dose every 24 hours	Duration (days)
Acute Bacterial Sinusitis	400 mg	10
Acute Bacterial Exacerbation of Chronic Bronchitis	400 mg	5
Community Acquired Pneumonia	400 mg	7-14
Uncomplicated Skin and Skin Structure Infections	400 mg	7
Complicated Skin and Skin Structure Infections	400 mg	7-21
Complicated Intra-Abdominal Infections	400 mg	5-14

Iventi™ 400 IV should be administered by intravenous infusion over a period of 60 minutes. Avoid bolus or rapid infusion.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. Because no adequate or well-controlled studies have been conducted in pregnant women, Moxifloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Moxifloxacin is excreted in the breast milk of rats. Moxifloxacin may also be excreted in human milk. Because of the potential for serious adverse reactions in infants who are nursing from mothers taking Moxifloxacin, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

PEDIATRIC USE

Safety and effectiveness in pediatric patients and adolescents less than 18 years of age have not been established.

GERIATRIC USE

Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture when being treated with a fluoroquinolone such as Moxifloxacin. This risk is further increased in patients receiving concomitant corticosteroid therapy.

SIDE EFFECT

Treatment with Moxifloxacin (PO, IV or sequential therapy) may cause some side effects. Common (≥1%) side effects include headache, nausea, vomiting, diarrhea, constipation, abdominal pain, dyspepsia, dizziness, pyrexia and insomnia etc. Less common (0.1 to <1%) side effects include neutropenia, palpitations, tachycardia, bradycardia, vertigo, tinnitus, dry mouth, gastritis, edema, fatigue, malaise, hyperglycemia, anorexia, hyperlipidemia, hypoglycemia, dehydration, back pain and arthralgia etc.

CONTRAINDICATION

Moxifloxacin is contraindicated in persons with known hypersensitivity to Moxifloxacin or other quinolone antibacterials.

DRUG INTERACTION

There are no data concerning an interaction of intravenous fluoroquinolones with oral antacids, sucralfate, multivitamins, didanosine, or metal cations. However, no fluoroquinolone should be co-administered with any solution containing multivalent cations, e.g., magnesium, through the same intravenous line. Quinolones, including Moxifloxacin, have been reported to enhance the anticoagulant effects of warfarin or its derivatives in the patient population. Although not observed with Moxifloxacin in preclinical and clinical trials, the concomitant administration of a nonsteroidal anti-inflammatory drug with a quinolone may increase the risks of CNS stimulation and convulsions. There is limited information available on the potential for a pharmacodynamic interaction in humans between Moxifloxacin and other drugs that prolong the QTc interval of the electrocardiogram. Sotalol, a Class III antiarrhythmic, has been shown to further increase the QTc interval when combined with high doses of intravenous (IV) Moxifloxacin in dogs. Therefore, Moxifloxacin should be avoided with Class IA and Class III antiarrhythmics.

PRECAUTION

Fluoroquinolones, including Moxifloxacin, are associated with an increased risk of tendinitis and tendon rupture in all ages. The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants. Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in persons with myasthenia gravis. Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Moxifloxacin, and may range in severity from mild diarrhea to fatal colitis.

INSTRUCTION FOR THE USE OF Iventi™ 400 IV

1. Check the bag for minute leaks by squeezing the inner bag firmly. If leaks are found, or if seal is not intact, discard the solution.
2. Do not use if the solution is cloudy or a precipitate is present.
3. Do not use flexible bags in series connections.
4. Close flow control clamp of administration set.
5. Remove cover from port at bottom of bag.
6. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated.
7. Suspend bag from hanger.
8. Squeeze and release drip chamber to establish proper fluid level in chamber during infusion of **Iventi™ 400 IV.**
9. Open flow control clamp to expel air from set. Close clamp.
10. Regulate the rate of administration with flow control clamp.

STORAGE

Store below 25°C and protect from light. Avoid extreme heat and freezing. Keep out of reach of children.

HOW SUPPLIED

Iventi™ 400 IV: Box contains 1 bag of 250 ml sterile solution for intravenous infusion.

Manufactured by :

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH

TM-Trade Mark.

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