

Composition:

Optimox® Tablet: Each film coated tablet contains Moxifloxacin Hydrochloride BP equivalent to Moxifloxacin 400 mg.

Optimox® IV Infusion: Each 250 ml sterile solution contains Moxifloxacin Hydrochloride BP equivalent to Moxifloxacin 400 mg.

Pharmacology:

Moxifloxacin is a member of the fluoroquinolone class of antibacterial agents. It has broad spectrum of activity and antibacterial action. It exerts activity against a wide range of gram-positive, gram-negative, anaerobic and atypical bacteria including *Mycoplasma pneumoniae*. The bactericidal action results from the inhibition of topoisomerase II (DNA gyrase) and topoisomerase IV which are required for bacterial DNA replication, transcription & repair.

Indications:

Optimox® is indicated for treating the following infections caused by susceptible bacteria-

- Community acquired pneumonia
- Exacerbation of chronic bronchitis
- Sinusitis
- Skin and soft tissue infections
- Pelvic inflammatory disease
- Complicated intra-abdominal infections etc.

Dosage and administration:

Tablet & IV Infusion:

The dose of **Optimox®** is 400 mg (orally or as an intravenous infusion) once every 24 hours. The duration of therapy depends on the type of infections as described in the following table:

Indications	Dose	Duration
Community Acquired Pneumonia	400 mg	7-14 days
Exacerbation of chronic bronchitis	400 mg	5-10 days
Sinusitis	400 mg	7-10 days
Skin and soft tissue infections	400 mg	7-21 days
Pelvic inflammatory diseases	400 mg	14 days
Complicated intra-abdominal infections	400 mg	5-14 days

Optimox® IV Infusion can be administered intravenously for the entire treatment duration. Alternatively, therapy may be initial intravenous administration, followed by oral administration when clinically indicated. No dosage adjustment is required in patients with renal or hepatic impairment.

Administration Instructions:

Tablet:

One **Optimox®** Tablet once a day.

IV Infusion:

1. Before use please check the bottle against a light source prior to administration.
2. Do not use if the solution is turbid or contains particles.
3. **Optimox® IV** should be administered by intravenous infusion over period of 60 minutes.
4. Avoid bolus or rapid infusion.
5. Discard any unused portion.
6. Do not refrigerate.

Contraindications:

Moxifloxacin is contraindicated in the patients with known hypersensitivity to moxifloxacin or other quinolones.

Precautions:

Moxifloxacin has been shown to prolong the QT interval in some patients. It should be avoided in patients with known prolongation, hypokalemia and with drugs that prolong the QT interval. It may cause increased risk of tendinitis and tendon rupture. It should be discontinued if pain or inflammation in a tendon occurs.

Side effects:

Most side effects reported with moxifloxacin treatment are mild to moderate in nature and require no treatment. Most common adverse reactions are nausea, diarrhea, headache, dizziness, retinal detachment, tendinitis & tendon rupture.

Use in special groups:

Pregnancy: Pregnancy category C drug. 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.

Nursing mothers: Moxifloxacin may be excreted in the human breast milk. Because of the potential for serious adverse reactions in infants 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 patients: Safety and effectiveness in pediatric patients and adolescent less than 18 years of age have not been established.

Drug interactions:

Antacids, sucralfate, multivitamins and other products containing multivalent cations reduces the absorption of moxifloxacin. Moxifloxacin should be administered 4 hours before or 8 hours after antacids, sucralfate, multivitamins and other products with multivalent cations. It may enhance anticoagulant effect of warfarin and proarrhythmic effect of Class IA and Class III antiarrhythmics. So concomitant use of moxifloxacin with them should be avoided. No clinically significant drug interactions of theophylline, digoxin, or glyburide have been observed with moxifloxacin.

Storage:

- Store below 30°C, keep in dry place & protect from light.
- Keep out of the reach of children.

Packing:

Optimox® Tablet: Each box contains 10 tablets in blister pack.

Optimox® IV Infusion: Each box contains 250 ml bottle of sterile solution for IV Infusion.

Manufactured by:



ARISTOPHARMA LTD.
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