Moxiflen Tablets

(USP Specification)

Moxifloxacin HCl **400mg**

(USP Specifications)

Presentation

Moxiflen Tablet:

Each film coated tablet contains:

Moxifloxacin HCl eq. to Moxifloxacin.....400mg

Description

Moxiflen is an 8-methoxy-fluoroquinolone antibiotic with a broad spectrum of activity and bactericidal action. **Moxiflen** has in vitro activity against a wide range of Gram-positive and Gram-negative organisms, anaerobes, acid-fast bacteria, and atypicals e.g. Chlamydia spp., Mycoplasma spp. and Legionella spp. The bactericidal action results from the interference with topoisomerase II and IV. Topoisomerases are essential enzymes that control DNA topology and assist in DNA replication, repair and transcription. Moxifloxacin is effective against b-lactam and macrolide resistant bacteria.

Indications

Moxiflen tablet are indicated for the treatment of the following bacterial infections caused by susceptible strains:

- Bronchitis (acute exacerbations of chronic bronchitis)
- Pneumonia (community acquired)
- Sinusitis (acute)
- Complicated skin and skin structure infections (including diabetic foot infections)
- Typhoid fever/ Enteric fever
- Complicated intra-abdominal infections including polymicrobial infections such as abscesses

Moxiflen tablets are indicated for the treatment of the following bacterial infections caused by susceptible strains: Uncomplicated pelvic inflammatory disease (i.e. infections of female upper genital tract, including salpingitis and endometritis)

Dosage and Administration

The recommended dose for **Moxiflen** tablet is 400 mg once daily for the above-mentioned indications and should not be exceeded.

- Bronchitis: acute exacerbation of chronic bronchitis, 5 days
- Pneumonia: community acquired pneumonia, 10 days
- Sinusitis: acute sinusitis, 7 days
- Complicated skin and skin structure infections total treatment duration for sequential therapy (intravenous followed by oral therapy): 7 - 21 days
- Typhoid fever/ Enteric fever: 7 - 10 days
- Uncomplicated pelvic inflammatory disease: 14 days
- Complicated intra-abdominal infections total treatment duration for sequential therapy (intravenous followed by oral therapy): 5-14 days

Alternatively, therapy may be initial intravenous administration, followed by oral administration of tablets when clinically indicated. The recommended duration of treatment for the indication being treated should not be exceeded. **Elderly:** No adjustment of dosage is required in the elderly. **Children:** Efficacy and safety of **Moxiflen** in children and adolescents have not been established

Side Effects

The following undesirable effects have a higher frequency in the subgroup of IV/oral sequentially treated patients: Common: Increased gamma-glutamyl-transferase. Uncommon: Ventricular tachyarrhythmias, hypotension, oedema, vasodilatation, antibiotic associated colitis (in very rare cases associated with life threatening complications), seizures of various clinical manifestations (incl. grand mal convulsions), hallucination, renal impairment and renal failure (due to dehydration, especially in elderly with pre-existing renal disorders).

Adverse Drug Reaction

Risk of Retinal detachment.

Contraindications

Known hypersensitivity to any component of moxifloxacin or other quinolones or any of the excipients. Patients below 18 years of age.

Precautions and Warning

In some instances, the hypersensitivity and allergic reactions occurred after the first administration. Anaphylactic reactions in very rare instances can progress to a life-threatening shock, in some instances after the first administration. In these cases, the treatment with **Moxiflen** must be discontinued, medical treatment (e.g. treatment for shock) is required. Moxifloxacin has been shown to prolong the QT interval of the electrocardiogram in some patients. As women tend to have a longer baseline QTc interval compared with men, they may be more sensitive to QTc-prolonging medications. Elderly patients may also be more susceptible to drug-associated effects on the QT interval. The medicine should be avoided in patients with known prolongation of the QT interval, patients with uncorrected hypokalaemia and patients receiving class IA (e.g. quinidine, procainamide) or class III (e.g. amiodarone, sotalol) antiarrhythmic agents, due to the lack of clinical experience with the medicine in these patient populations. An additive effect of moxifloxacin and medicines that prolong the QT interval such as cisapride, erythromycin, antipsychotics, and tricyclic antidepressants cannot be excluded; therefore, moxifloxacin should be used with caution when given concurrently with these medicines. **Moxiflen** should be used with caution in patients with liver cirrhosis as pre-existing QT prolongation in these patients cannot be excluded. **Moxiflen** should be used with caution in patients with ongoing proarrhythmic conditions (especially women and elderly patients), such as clinically significant bradycardia, acute myocardial ischaemia. As the magnitude of QT prolongation may increase with increasing concentrations of the medicine, the recommended dose and the infusion rate (400 mg within 60 minutes) should not be exceeded. However, in patients suffering from pneumonia no correlation between plasma concentrations of moxifloxacin and QTc prolongation was observed. QT prolongation may lead to an increased risk for ventricular arrhythmias including torsades de pointes. No cardiovascular morbidity or mortality attributable to QTc prolongation occurred with moxifloxacin treatment in clinical studies with more than 9000 patients; however certain predisposing conditions may increase the risk for ventricular arrhythmias. Seizures may occur with quinolone therapy. **Moxiflen** should be used with caution in patients with known or suspected CNS disorders, which may predispose to seizures or lower the seizure threshold. Tendon inflammation and rupture may occur with quinolone therapy including moxifloxacin, particularly in elderly patients and in those treated concurrently with corticosteroids. At the first sign of pain or inflammation, patients should discontinue treatment and rest the affected limb(s). Quinolones have been shown to cause photosensitivity reactions in patients. However, in specially designed preclinical and clinical studies photosensitivity has not been observed with moxifloxacin.

Use in Pregnancy & Lactation

The safe use of moxifloxacin in human pregnancy has not been established. Animal studies have shown reproductive toxicity. The potential risk for humans is unknown. Consequently, the use of moxifloxacin during pregnancy is contraindicated. Preclinical evidence indicates that small amounts of moxifloxacin may be secreted in human milk. There is no data available in lactating or nursing women. Therefore, the use of moxifloxacin in nursing mothers is contraindicated.

Drug Interactions

Itraconazole: Exposure (AUC) to itraconazole was only marginally altered under concomitant moxifloxacin treatment. Pharmacokinetics of moxifloxacin were not significantly altered by itraconazole. No dose adjustment is necessary for itraconazole when given with moxifloxacin and vice versa. **Charcoal:** Concomitant dosing of charcoal and 400 mg oral moxifloxacin reduced the systemic availability of the medicine by more than 80% by preventing absorption in vivo.

Storage Conditions:

Store at 20°C-25°C. Protect from light and moisture.(excursions permitted to 15°C-30°C).

Keep all medicines out of the reach of children.

How Supplied :

Moxiflen tablets are available in a blister pack of 5 Film Coated tablets.

Contains Lactose But Gluten Free

NEXT PHARMACEUTICAL

Manufactured by:
NEXT Pharmaceutical Products (Pvt.) Ltd.
Plot no. 44-A&B, Sunder Industrial Estate Lahore-Pakistan

موکسیفلن

(موکسیفلوکساسن ہائیڈروکلورائیڈ)

400 ملی گرام

5 فلم کوٹڈ گولیاں

خوراک وہدایات

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت کی جائے۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

دوا کو 20°C-25°C درجہ حرارت پر نمی اور روشنی سے محفوظ رکھیں۔

(درجہ حرارت کی حد 15°C سے 30°C ہے۔)