



**Moxavidex**  
**Moxifloxacin hydrochloride 400 mg**  
**Film coated tablets- Broad spectrum antibiotic**

### **1 INDICATIONS and USAGE**

Fluoroquinolones should be reserved for use in patients who have no other treatment options for acute bacterial sinusitis, (ABS) and acute bacterial exacerbation of chronic bronchitis (ABECB).

#### **1.1 Community Acquired Pneumonia**

**Moxavidex** tablets are indicated in adult patients for the treatment of Community Acquired Pneumonia caused by susceptible isolates of *Streptococcus pneumoniae* (including multi-drug resistant *Streptococcus pneumoniae* [MDRSP]), *Haemophilus influenzae*, *Moraxella catarrhalis*, methicillin-susceptible *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Mycoplasma pneumoniae*, or *Chlamydomphila pneumonia*. Used only when other antibiotic treatment cannot be used.

#### **1.2 Uncomplicated Skin and Skin Structure Infections**

**Moxavidex** tablets are indicated in adult patients for the treatment of Uncomplicated Skin and Skin Structure Infections caused by susceptible isolates of methicillin- susceptible *Staphylococcus aureus* or *Streptococcus pyogenes*.

#### **1.3 Complicated Skin and Skin Structure Infections**

**Moxavidex** is indicated in adult patients for the treatment of Complicated Skin and Skin Structure Infections caused by susceptible isolates of methicillin-susceptible *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella pneumoniae*, or *Enterobacter cloacae*

#### **1.4 Complicated Intra-Abdominal Infections**

**Moxavidex** tablets are indicated in adult patients for the treatment of Complicated Intra-Abdominal Infections (cIAI) including polymicrobial infections such as abscess caused by susceptible isolates of *Escherichia coli*, *Bacteroides fragilis*, *Streptococcus anginosus*, *Streptococcus constellatus*, *Enterococcus faecalis*, *Proteus mirabilis*, *Clostridium perfringens*, *Bacteroides thetaiotaomicron*, or *Peptostreptococcus* species.

#### **1.5 Plague**

**Moxavidex** tablets are indicated in adult patients for the treatment of plague, including pneumonic and septicemic plague, due to susceptible isolates of *Yersiniapestis* and

prophylaxis of plague in adult patients. Efficacy studies of moxifloxacin could not be conducted in humans with plague for feasibility reasons. Therefore, this indication is based on an efficacy study conducted in animals only.

### 1.6 Acute Bacterial Sinusitis

**Moxavidex** tablets are indicated in adult patients (18 years of age and older) for the treatment of Acute Bacterial Sinusitis (ABS) caused by susceptible isolates of *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis*.

Because fluoroquinolones, including moxifloxacin hydrochloride tablets, have been associated with serious adverse reactions [see *Warnings and Precautions (5.1-5.13)*] and for some patients ABS is self-limiting, reserve moxifloxacin hydrochloride tablets for treatment of ABS in patients who have no alternative treatment options.

### 1.7 Acute Bacterial Exacerbation of Chronic Bronchitis

**Moxavidex** tablets are indicated in adult patients for the treatment of Acute Bacterial Exacerbation of Chronic Bronchitis (ABECB) caused by susceptible isolates of *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, methicillin susceptible *Staphylococcus aureus*, or *Moraxella catarrhalis*.

Because fluoroquinolones, including moxifloxacin hydrochloride tablets, have been associated with serious adverse reactions and for some patients ABECB is self-limiting, reserve moxifloxacin hydrochloride tablets for treatment of ABECB in patients who have no alternative treatment options.

### 1.8 Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of **Moxavidex** and other antibacterial drugs, Moxifloxacin hydrochloride should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

#### **Fluoroquinolones should not be used in the following indications:**

To treat infections that might get better without treatment or are not severe (such as throat infections);

To treat non-bacterial infections, e.g. non-bacterial (chronic) prostatitis;

For preventing traveler's diarrhoea or recurring lower urinary tract infections (urine infections that do not extend beyond the bladder);

To treat mild or moderate bacterial infections unless other antibacterial medicines commonly recommended for these infections cannot be used.

## 2 DOSAGE AND ADMINISTRATION

### 2.1 Dosage in Adult Patients

The dose of **Moxavidex** tablets is 400 mg (orally) once every 24 hours. The duration of therapy depends on the type of infection as described in Table 1.

**Table 1: Dosage and Duration of Therapy in Adult Patients**

Type of Infection <sup>a</sup>	Dose Every 24 hours	Duration (days) <sup>b</sup>
Community Acquired Pneumonia (1.1)	400 mg	7 to 14

Uncomplicated Skin and Skin Structure Infections (SSSI) (1.2)	400 mg	7
Complicated SSSI (1.3)	400 mg	7 to 21
Complicated Intra-Abdominal Infections (1.4)	400 mg	5 to 14
Plague (1.5) <sup>c</sup>	400 mg	10 to 14
Acute Bacterial Sinusitis (ABS) (1.6)	400 mg	10
Acute Bacterial Exacerbation of Chronic Bronchitis (ABECB) (1.7)	400 mg	5

a) Due to the designated pathogens [see *Indications and Usage (1)*].

b) Sequential therapy (oral) may be instituted at the discretion of the physician.

c) Drug administration should begin as soon as possible after suspected or confirmed exposure to *Yersinia pestis*.

## 2.2 Important Administration Instructions

**Moxavidex Tablets with Multivalent Cations:** Administer Moxifloxacin at least 4 hours before or 8 hours after products containing magnesium, aluminum, iron or zinc, including antacids, sucralfate, multivitamins and didanosine buffered tablets for oral suspension or the pediatric powder for oral solution.

With Food **Moxavidex** Tablets can be taken with or without food, drink fluids liberally.

## 3 DOSAGE FORMS AND STRENGTHS

**Moxavidex Tablets** are film coated tablets contain 400 mg Moxifloxacin Hydrochloride.

## 4 CONTRAINDICATIONS

**Moxavidex** is contraindicated in persons with a history of hypersensitivity to moxifloxacin or any member of the quinolone class of antibacterial.

History of tendon disorders related to fluoroquinolone administration.

## 5 Storage

Store at temperature not exceeding 30°C in a dry place.

Keep out of reach of children

## 6 Package:

Carton box contains 1 or 2 (Al / transparent PVDC) strip of 5 film coated tablets with insert leaflet.