





Ciproloxacin 500mg Film-coated tablets

Broad-spectrum antibiotic

Keep medicine out of reach of children. Read the leaflet insert carefully before use.

For further information please ask Doctor's advice.

Composition

Active ingredient: Each film-coated tablet contains 500 mg ciprofloxacin as hydrochloride.

Excipients: Film-coat Cellulose microcrystalline, Croscarmellose, Maize starch, Magnesium stearate, Silica colloidal anhydrous.

Pharmaceutical form: Ciprobay film-coated tablets marked with 'CIP 500 score 500' on one side and 'BAYER' on the reverse side.

Indications: Ciprofloxacin is used as an adjuvant treatment for pneumonias caused by Klebsiella spp., Enterobacter spp., Proteus spp., Escherichia coli, Pseudomonas aeruginosa, Haemophilus spp., Moraxella catarrhalis, Legionella spp., and staphylococci.

Contraindications: Ciprofloxacin is contraindicated in patients with known hypersensitivity to ciprofloxacin or any of its excipients.

Warnings: Ciprofloxacin may cause tendonitis and tendon rupture, peripheral neuropathy, and central nervous system effects.

Interactions: Ciprofloxacin may interact with theophylline, warfarin, and other drugs.

Pregnancy and lactation: Ciprofloxacin is not recommended during pregnancy and lactation.

Effects on ability to drive or operate machinery: Ciprofloxacin may affect the ability to drive or operate machinery.

Overdose: In the event of acute overdose, supportive care should be provided.

Pharmacological properties: Ciprofloxacin is a synthetic broad-spectrum fluoroquinolone antibiomatic agent.

Pharmacodynamic properties: Ciprofloxacin is a bactericidal agent with a broad spectrum of activity.

Pharmacokinetics: Ciprofloxacin is rapidly absorbed and reaches peak plasma concentrations within 1-2 hours.

Toxicology: Ciprofloxacin is well tolerated in clinical studies, with adverse effects being generally mild and transient.

Stability: Ciprofloxacin tablets are stable under normal storage conditions.

Other information: Ciprofloxacin is a prescription medicine and should be used under medical supervision.

Additional information: Ciprofloxacin is a registered trademark of Bayer AG.

Legal notice: This leaflet contains information about the medicinal product Ciprobay.

Table 1: Recommended daily doses of Ciprobay Oral in children and adolescents.

Table 1: Recommended daily doses of Ciprobay Oral in children and adolescents. Columns: Indications, Daily dose of ciprofloxacin in mg for Ciprobay film-coated tablets.

Table 1: Recommended daily doses of Ciprobay Oral in children and adolescents

Table 1: Recommended daily doses of Ciprobay Oral in children and adolescents. Columns: Indications, Daily dose of ciprofloxacin in mg for Ciprobay oral.

Table 2: Recommended doses for patients with renal impairment.

Table 2: Recommended doses for patients with renal impairment. Columns: Creatinine Clearance (mL/min/1.73 m²), Serum Creatinine (µmol/L), Total daily oral dose of ciprofloxacin (mg).

Table 3: Recommended doses for patients with hepatic impairment.

Table 4: Recommended doses for patients with hepatic impairment.

Table 5: Recommended doses for patients with hepatic impairment.

Table 6: Recommended doses for patients with hepatic impairment.

Table 7: Recommended doses for patients with hepatic impairment.

Table 8: Recommended doses for patients with hepatic impairment.

Table 9: Recommended doses for patients with hepatic impairment.

Table 10: Recommended doses for patients with hepatic impairment.

Table 11: Recommended doses for patients with hepatic impairment.

Table 12: Recommended doses for patients with hepatic impairment.

Table 13: Recommended doses for patients with hepatic impairment.

Table 14: Recommended doses for patients with hepatic impairment.

Table 15: Recommended doses for patients with hepatic impairment.

Table 16: Recommended doses for patients with hepatic impairment.

Table 17: Recommended doses for patients with hepatic impairment.

Table 18: Recommended doses for patients with hepatic impairment.

Table 19: Recommended doses for patients with hepatic impairment.

Table 20: Recommended doses for patients with hepatic impairment.

Table 21: Recommended doses for patients with hepatic impairment.

Table 22: Recommended doses for patients with hepatic impairment.

Table 23: Recommended doses for patients with hepatic impairment.

Table 24: Recommended doses for patients with hepatic impairment.

Table 25: Recommended doses for patients with hepatic impairment.

Table 26: Recommended doses for patients with hepatic impairment.

Table 27: Recommended doses for patients with hepatic impairment.

Children and adolescents: As with medicinal products in its class, ciprofloxacin has been shown to cause arthropathy in weight-bearing joints of immature animals.

Phenyltoin: Altered (decreased or increased) serum levels of phenytoin were observed in patients receiving Ciprobay and phenytoin simultaneously.

Methotrexate: Renal tubular transport of methotrexate may be inhibited by concomitant administration of Ciprobay, potentially leading to increased plasma levels.

NSAID: Simultaneous administration of Ciprobay with a non-steroidal anti-inflammatory drug (NSAID) may increase the risk of methotrexate-associated toxic reactions.

Cyclosporin: A transient rise in the concentration of serum creatinine was observed when ciprofloxacin and cyclosporin containing medicinal products were administered simultaneously.

Gastrointestinal System: In the event of severe and persistent diarrhea during or after treatment, a physician should be consulted since this symptom can hide a serious intestinal disease.

Hepatitis: Cases of hepatic necrosis and life-threatening hepatic failure have been reported with Ciprobay. In the event of any signs and symptoms of hepatic disease (such as anorexia, jaundice, dark urine, pruritus, or tender abdomen), treatment should be discontinued.

Myasthenia Gravis: Ciprobay should be used with caution in patients with myasthenia gravis, because symptoms can be exacerbated.

Tendinitis and tendon rupture: Tendinitis and tendon rupture (predominantly Achilles tendon), sometimes bilateral, may occur with Ciprobay, even within the first 48 hours of treatment.

Seizures: Ciprobay, like other fluoroquinolones, is known to trigger seizures or lower the seizure threshold in epileptic and patients who have suffered from previous central nervous system (CNS) diseases.

Psychiatric reactions: Psychiatric reactions may occur even after the first administration of fluoroquinolones, including Ciprobay. In rare cases, depression or psychotic reactions can progress to suicidal ideations/thoughts and self-harming behavior.

Peripheral neuropathy: Ciprobay is associated with cases of QT prolongation (see 'Undesirable effects'). As women tend to have a longer baseline QTc interval compared with men, they may be more sensitive to QT-prolonging medications.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Altered (decreased or increased) serum levels of phenytoin were observed in patients receiving Ciprobay and phenytoin simultaneously.

Methotrexate: Renal tubular transport of methotrexate may be inhibited by concomitant administration of Ciprobay, potentially leading to increased plasma levels.

NSAID: Simultaneous administration of Ciprobay with a non-steroidal anti-inflammatory drug (NSAID) may increase the risk of methotrexate-associated toxic reactions.

Cyclosporin: A transient rise in the concentration of serum creatinine was observed when ciprofloxacin and cyclosporin containing medicinal products were administered simultaneously.

Gastrointestinal System: In the event of severe and persistent diarrhea during or after treatment, a physician should be consulted since this symptom can hide a serious intestinal disease.

Hepatitis: Cases of hepatic necrosis and life-threatening hepatic failure have been reported with Ciprobay. In the event of any signs and symptoms of hepatic disease (such as anorexia, jaundice, dark urine, pruritus, or tender abdomen), treatment should be discontinued.

Myasthenia Gravis: Ciprobay should be used with caution in patients with myasthenia gravis, because symptoms can be exacerbated.

Tendinitis and tendon rupture: Tendinitis and tendon rupture (predominantly Achilles tendon), sometimes bilateral, may occur with Ciprobay, even within the first 48 hours of treatment.

Seizures: Ciprobay, like other fluoroquinolones, is known to trigger seizures or lower the seizure threshold in epileptic and patients who have suffered from previous central nervous system (CNS) diseases.

Psychiatric reactions: Psychiatric reactions may occur even after the first administration of fluoroquinolones, including Ciprobay. In rare cases, depression or psychotic reactions can progress to suicidal ideations/thoughts and self-harming behavior.

Peripheral neuropathy: Ciprobay is associated with cases of QT prolongation (see 'Undesirable effects'). As women tend to have a longer baseline QTc interval compared with men, they may be more sensitive to QT-prolonging medications.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Food and Dairy Products: The concurrent administration of dairy products or mineral-fortified drinks alone (e.g. milk, yogurt, calcium-fortified orange juice) and Ciprobay should be avoided because of absorption of ciprofloxacin.

Drugs known to prolong QT interval: Ciprobay, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III antiarrhythmics, lidocaine, procainamide, macrolides, antipsychotics).

Chelation Complex Formation: The simultaneous administration of Ciprobay and multivalent cation-containing medicinal and mineral supplements (e.g. calcium, magnesium, zinc, aluminum, iron, polymeric phosphate binders) can reduce the absorption of ciprofloxacin.

Table 4: ADRs table. Columns: System Organ Class, Common, Uncommon, Rare, Very Rare, Not Known.

Table 4: ADRs table

Table 4: ADRs table. Columns: System Organ Class, Common, Uncommon, Rare, Very Rare, Not Known.

Table 4: ADRs table

Table 4: ADRs table. Columns: System Organ Class, Common, Uncommon, Rare, Very Rare, Not Known.

Table 5: In vitro susceptibility to ciprofloxacin. Columns: Organism, MIC50, MIC90, % of isolates susceptible.

Table 5: In vitro susceptibility to ciprofloxacin

Table 5: In vitro susceptibility to ciprofloxacin. Columns: Organism, MIC50, MIC90, % of isolates susceptible.

Table 5: In vitro susceptibility to ciprofloxacin

Table 5: In vitro susceptibility to ciprofloxacin. Columns: Organism, MIC50, MIC90, % of isolates susceptible.

Table 6: Acute bacterial sinusitis. Columns: Study, Dose, Success rate.

Table 6: Acute bacterial sinusitis

Table 6: Acute bacterial sinusitis. Columns: Study, Dose, Success rate.

Table 6: Acute bacterial sinusitis

Table 6: Acute bacterial sinusitis. Columns: Study, Dose, Success rate.

Table 6: Acute bacterial sinusitis. Columns: Study, Dose, Success rate.

Table 6: Acute bacterial sinusitis

Table 6: Acute bacterial sinusitis. Columns: Study, Dose, Success rate.

Table 6: Acute bacterial sinusitis

Table 6: Acute bacterial sinusitis. Columns: Study, Dose, Success rate.

Table 6: Acute bacterial sinusitis. Columns: Study, Dose, Success rate.

Table 6: Acute bacterial sinusitis

Table 6: Acute bacterial sinusitis. Columns: Study, Dose, Success rate.

Table 6: Acute bacterial sinusitis

Table 6: Acute bacterial sinusitis. Columns: Study, Dose, Success rate.