User information **Please read carefully!**

Ciprobay® 750

Active ingredient: ciprofloxacin
Film-coated tablets

Broadspectrum antibiotic

Composition
1 film-coated tablet contains 873 mg ciprofloxacin hydrochloride monohydrate, corresponding to 750 mg ciprofloxacin.

Other constituents: microcrystalline cellulose, maize starch, poly(1-vinyl-2-pyrrolidone) cross-linked with opening of the ring, colloidal silicon dioxide, magnesium stearate, methylhydroxypropylcellulose, Macrogol 4000, titanium (IV) oxide (E 171).

Indications
Complicated infections caused by organisms sensitive to ciprofloxacin:

Infections of the
- Respiratory tract. In pneumococcal lung inflammations (pneumonia) treated by a GP Ciprobay 750 is not the drug of first choice. The use of Ciprobay 750 may, however, be indicated if so-called problem organisms are found to be responsible (e.g. Klebsiella, Enterobacter, Proteus, Pseudomonas, Legionella, Staphylococcus, Escherichia coli).
- Middle ear (otitis media) and paranasal sinuses (sinusitis), particularly where these are caused by gram-negative organisms including Pseudomonas or Staphylococcus. **Ciprobay 750 therefore must not be used in acute tonsillitis (angina tonsillaris).**
- Eyes
- Skin and soft tissue
- Bones and joints.

Peritonitis

Blood poisoning (sepsis)

Infections or imminent risk of infection (prophylaxis) in patients with a weakened immune system, e.g. patients receiving treatment with drugs which inhibit the immune system (immunosuppressants) or patients with a reduced white blood cell count (neutropenia).

According to investigations outside the living organism (in vitro), the following organisms can be regarded as sensitive:
E. coli, Shigella, Salmonella, Citrobacter, Klebsiella, Enterobacter, Serratia, Hafnia, Edwardsiella, Proteus (indole-positive and indole-negative), Providencia, Morganella, Yersinia; Vibrio, Aeromonas, Plesiomonas, Pasteurella, Haemophilus, Campylobacter, Pseudomonas, Legionella, Neisseria, Moraxella, Branhamella, Acinetobacter, Brucella; Staphylococcus, Listeria, Corynebacterium, Chlamydia.

The following organisms show varying degrees of sensitivity:
Gardnerella, Flavobacterium, Alcaligenes, Streptococcus agalactiae, Streptococcus faecalis, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus viridans, Mycoplasma hominis, Mycobacterium tuberculosis, and Mycobacterium fortuitum.

The following organisms are generally resistant:
Streptococcus faecium, Ureaplasma urealyticum, Nocardia asteroides.

With a few exceptions, anaerobes are moderately sensitive (e.g. Peptococcus, Peptostreptococcus) to resistant (e.g. Bacteroides).

Ciprobay 750 is ineffective against Treponema pallidum.

Contraindications
Contraindications are diseases or circumstances in which certain drugs must not be administered or should be administered only after careful assessment by the doctor, as in these cases the possible damage in general outweighs the expected benefits. In order to make a careful check for the presence of contraindications, the doctor must therefore be informed about all previous and concomitant illnesses, any concomitant treatment, and your particular circumstances and lifestyle. Contraindications may also arise or emerge only after the beginning of treatment with this drug, and in these cases too your doctor should be informed.

Ciprobay 750 must not be used in cases of hypersensitivity to ciprofloxacin or to other drugs from the same class of substances (quinolones, gyrase inhibitors). Ciprobay 750 must not be prescribed to growing children or adolescents, to pregnant women, or to nursing mothers, since there is no experience with the drug's safety in these patient groups and since animal studies indicate that damage to articular cartilage in the immature organism cannot be fully excluded. Animal studies have not yielded any evidence of teratogenic effects (malformations).

Note
In patients who suffer from seizures (epileptics) and patients with other existing damage to the central nervous system (e.g. reduced convulsion threshold, history of convulsions, reduced cerebral blood flow, changes in brain structure, or stroke) Ciprobay 750 should only be used after a careful consideration of the risks and the benefits, as these patients may be at risk from central-nervous side effects.

There may be an increase in metabolic products in the blood (urea, creatinine, bilirubin, and glucose).
In isolated cases crystals or red blood cells have been observed in the urine (crystalluria and haematuria).

Note for drivers
Even when used in accordance with the instructions, this product may affect the speed of reaction to such a degree that the ability to drive or to operate machinery is impaired. The effect is intensified by combination with alcohol.

Interactions
The effects of some drugs can be influenced by simultaneous use of other drugs. For this reason you should inform your doctor if you are continuing to take other drugs, have taken other drugs until recently, or wish to take other drugs at the same time as Ciprobay 750. Your doctor will be able to tell you whether under these circumstances intolerance can be expected and whether any special measures will be necessary if you take this drug.

Simultaneous administration of Ciprobay 750 and iron, sucralfate, or antacids containing magnesium, aluminium, or calcium reduces the absorption of Ciprobay 750. Ciprobay 750 should therefore be taken either 1–2 h **before** or at least 4 h **after** these products. This restriction does not apply to antacids of the H_2-receptor blocker type.

Simultaneous administration of Ciprobay 750 and theophylline can cause an undesirable rise in the serum theophylline concentration. This can lead to theophylline-determined side effects. If simultaneous use of the two products cannot be avoided, the serum concentrations of theophylline should be checked and the theophylline dose appropriately reduced.

It is known from animal studies that the combination of very high doses of quinolones (gyrase inhibitors) and certain antiinflammatory drugs (nonsteroidal antiinflammatories) can provoke convulsions. This is not, however, the case with drugs containing acetylsalicylic acid.

After simultaneous administration of Ciprobay 750 and cyclosporin a transient rise in serum creatinine has been observed in isolated cases. For this reason very frequent monitoring of the serum creatinine level (twice weekly) is necessary in these patients.

Simultaneous administration of Ciprobay 750 and warfarin can intensify the action of the warfarin.

After simultaneous administration of Ciprobay 750 and glibenclamide the action of the glibenclamide can be intensified in isolated cases (lowering of blood glucose, hypoglycaemia).

Probenecid influences the excretion of Ciprobay in the urine. After simultaneous administration of Ciprobay and probenecid, the concentration of Ciprobay in the blood (serum) rises.

Metoclopramide reduces the uptake of Ciprobay into circulation, leading to maximum concentrations in the blood (serum) within a short time. No effect on availability in the human body (bioavailability) has been established.

Dosage
Unless otherwise prescribed, the following guideline dose is recommended:

Unit/daily dose for adults: 2 x 1 film-coated tablet

Older patients should receive as low a dose as possible, depending on the severity of the infection and creatinine excretion (clearance).

If, because of the severity of the illness or for other reasons, the patient is unable to take the film-coated tablets, it is recommended to begin treatment with the intravenous form of ciprofloxacin.

Impaired renal or liver function
1. Impaired renal function
   Creatinine clearance < 20 ml/min or serum creatinine > 3 mg/100 ml:
   2 x half the normal unit dose/day or
   1 x 1 normal unit dose/day.
2. Impaired renal function + haemodialysis
   Dosage as in 1., on haemolysis days after the intervention.
3. Impaired liver function
   No dose adjustment is required.
4. Impaired renal **and** liver function
   Dose adjustment as in 1., possibly determinations of Ciprobay 750 concentration in serum.

Side effects

In addition to the desired main effects, drugs can also exert undesirable effects, so-called side effects. Side effects which have been observed in chronological connection with the use of Ciprobay 750, but which do not necessarily occur in every patient, are listed below:

Effects on the gastrointestinal tract

Nausea, diarrhoea, vomiting, digestive disturbances, abdominal pain, flatulence, loss of appetite.

If severe and persistent diarrhoea occurs during or after treatment the doctor must be consulted, since this can mask a serious underlying intestinal disorder (pseudomembranous colitis) which requires immediate treatment. In such cases Ciprobay 750 must be discontinued and suitable therapy initiated (e.g. 4 x 250 mg vancomycin/day p.o.). Drugs which inhibit peristalsis must not be administered.

Effects on the nervous system

Dizziness, headache, tiredness, agitation, tremor; very rarely sleeplessness, sensory disturbances in the arms and the legs (peripheral), sweating, unsteady gait, convulsions, increase in intracranial pressure, anxiety states, nightmares, confusion, depression, hallucinations, in isolated cases psychotic reactions (right up to self-aggression). These reactions sometimes occurred after only one dose. In such cases Ciprobay 750 must be discontinued immediately and the treating physician must be informed.

Effects on the sense organs

Very rarely taste and smell disturbances, visual disturbances (e.g. double vision, seeing colours), tinnitus, temporary hearing difficulties, particularly at high frequencies.

Hypersensitivity reactions

The following reactions sometimes occurred after only one dose. In such cases Ciprobay 750 must be discontinued immediately and the treating physician must be informed.

Skin reactions such as rashes, pruritus, drug fever.

Very rarely:

- severe skin reactions, which may be life-threatening, which may be associated with disturbances of general health, fever, and inflamed reddening or vesicular lifting of the skin, lips, and mucosa (petechiae, haemorrhagic bullae, papules, vasculitis, Stevens-Johnson syndrome, Lyell's syndrome).
- kidney and liver damage (interstitial nephritis, hepatitis, liver-cell necrosis right through to life-threatening liver failure).
- immediate severe allergic reactions right through to shock (anaphylactic/anaphylactoid reactions), sometimes after only one dose. In such cases Ciprobay 750 must be discontinued immediately and medical treatment (e.g. shock therapy) initiated.
  The signs of shock include for example facial, vascular and laryngeal oedema, cold sweats, dyspnoea, dizziness and drowsiness, fast pulse rate, and a fall in blood pressure.

Effects on the cardiovascular system

Tachycardia; very rarely hot flushes, migraine, syncope.

Others

Articular complaints; very rarely a general feeling of weakness, muscle pains, tenosynovitis, light-sensitivity with reddening of the skin (photosensitivity), transient impairment of kidney function right through to temporary kidney failure.

Inflammation of the Achilles tendon has been observed in isolated cases during treatment with Ciprobay. Since this may lead to tendon rupture, if there is any evidence of inflammation of the Achilles tendon (e.g. painful swelling) Ciprobay 750 must be discontinued immediately and the doctor informed.

Repeated and long-term use of an antibiotic can lead to a renewed infection with the same pathogen, if the strain has developed resistance to the antibiotic. Superinfection with blastomycetes is also possible.

Effects on blood and blood constituents

Changes in blood cells or blood coagulation may occur (eosinophilia, leucocytopenia, granulocytopenia, anaemia, thrombocytopenia; very rarely leucocytosis, thrombocytosis, haemolytic anaemia, altered prothrombin values).

Influence on laboratory and urinary parameters

Liver function may be affected (increase in transaminases and alkaline phosphatase, right through to cholestatic jaundice) particularly in patients with existing liver damage.

Administration

The film-coated tablets are to be swallowed whole with a little liquid. They can be taken independently of mealtimes. The active substance is absorbed more quickly if the film-coated tablets are taken on an empty stomach.

Duration of use

The duration of treatment depends on the severity of the illness and on the clinical and bacteriological course. The treatment should in principle be continued systematically for at least 3 days after disappearance of the fever or of the clinical symptoms.

Average durations of treatment: over the entire period of the neutropenic phase (period with a reduced white blood cell count) in patients with weakened body defences, a maximum of 2 months in bone infections, and 7–14 days in all other infections.

In streptococcal infections the treatment must last at least 10 days because of the risk of late complications.

Note

Ciprobay 750 should not be used after the expiry date.

Bayer AG, Germany

Bayer

Supplementary information

Ciprobay® 750

Ciprofloxacin

Film-coated tablets

Broad-spectrum antibiotic

Properties

Ciprofloxacin is an active substance from the group of quinolones, developed by Bayer AG. These substances are also known as gyrase inhibitors.

Microbiology

Ciprobay has antibacterial activity against many gram-negative and gram-positive bacteria, anaerobic bacteria being generally less sensitive. Ciprobay prevents the information in the chromosome (heredity substance) necessary for normal bacterial metabolism from being read. This leads to a rapid decline in the reproductive capacity of the bacteria.

Ciprobay is also effective against bacteria which are resistant to other antibiotics outside the group of gyrase inhibitors. Therefore, Ciprobay is also highly effective against bacteria which are resistant, for example, to aminoglycosides, penicillins, cephalosporins, tetracyclines, and other antibiotics.

Clinical pharmacology

The absolute bioavailability of Ciprobay is 70–80 %. After oral administration the maximum blood concentrations are reached in 60–90 min. Ciprobay is present in high concentrations at the sites of infection, namely in the body fluids and tissues.

Presentation

Packs containing 10 and 20 film-coated tablets.
Hospital pack.

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers **Union of Arab Pharmacists**

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