M-Pro® Tablet
(Ciprofloxacin)
Broad-Spectrum Antibiotic

ایم-پرو® ٹیبلیٹ
(سپروفلوکساسن)

COMPOSITION
M-Pro.....250mg tablet
Each film coated tablet contains:
Ciprofloxacin Hydrochloride, U.S.P. equivalent to Ciprofloxacin....250mg.

M-Pro.....500mg tablet
Each film coated tablet contains:
Ciprofloxacin Hydrochloride, U.S.P. equivalent to Ciprofloxacin....500mg.

PROPERTIES
M-Pro (Ciprofloxacin) is a new drug from the quinolone group.These substances are also known as gyrase inhibitors.

MICROBIOLOGY
M-Pro has a strong antibacterial action against a broad spectrum of bacteria. It prevents transcription by the chromosome (genetic material) of the information needed for the normal metabolism of bacteria. This leads to a rapid decrease in the ability of bacteria to reproduce.
M-Pro is also characterized by the fact that as a result of its particular mode of action, it does not generally exhibit parallel resistance to any other antibiotic outside the gyrase inhibitor group. Therefore, M-Pro is highly effective against bacteria which are resistant, for example to aminoglycosides, penicillins, cephalosporins, tetracyclines and other antibiotics.

CLINICAL PHARMACOLOGY
The absolute bioavailability of M-Pro is 70-80%. The maximum blood concentration is reached just within 60-90 minutes after ingestion. M-Pro is present in high concentrations at the site of infection. i.e. in the body fluids and tissues. It only needs to be taken twice daily, in the morning and evening.

INDICATIONS
Infections:
Infection caused by pathogens, which are sensitive to Ciprofloxacin.
- Respiratory tract infection. In the treatment of outpatients with pneumonia due to pneumococcus. M-Pro should not be used as a first choice of drug. M-Pro can be regarded as an advisable treatment for pneumonias caused by klebsiella, Enterobacter, Proteus, Pseudomonas, Haemophilus, Branhamella, Legionella and Staphylococcus.
- Middle ear (otitis media), of the paranasal sinuses (sinusitis). especially if these are caused by gram-negative organisms including Pseudomonas or by Staphylococcus.
- Eye Infections.
- Kidneys and/or urinary tract.
- Reproductive organs, including gonorrhoea.
- Abdominal cavity (e.g. bacteria infections of the gastro-intestinal tract. biliary tract, peritonitis).
- Skin and soft tissues.
- Bones and Joints.

Septicaemia Infections, or imminent risk of infection (prophylaxis), in immuno-compromised patients (e.g those treated with immuno-suppressants patients with neutropenia). Administration for selective intestinal decontamination in patients treated with immuno-suppressants.
M-Pro has a bactericidal action. As a result of *in-vitro* investigations, the following pathogens may be regarded as sensitive to M-Pro: E- coli, Shigella Salmonella, Citrobacter, Klebsiella, Enterobacter, Serratia, Hafnia, Edwardsiella, Proteus (Indole-positive and indole negative). Providencia, morganella, Yersinia, Vibro, Aeromonas, Plesiomonas, Pasteurelle, Haemophilus, Campylobacter, Psedomonas, Legionella, Neisseria, Moraxelle, Branhamella, Acinetobacter, Brucella, Staphylococcus, Streptococcus agalactiae, Listeria, Corynebacterium, Chlamydia.

The following are sensitive in varying degrees: Gardnerella, Flavobacterium, Alcaligenes, Streptococcus faecalis, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus viridans, Mycoplasma hominis, Mycobacterium tuberculosis, and Mycobacterium fortuitum.
The following are generally resistant:
Streptococcus faecium. Ureaplasma urealyticum, Nocardia asteroides. Anaerobes, apart from a few exception, vary from being moderately sensitive (e.g. Peptococcus Peptostreptococcus) to resistant (e.g. Bacteroides).
M-Pro is not active against Treponema Pallidum.

CONTRA-INDICATIONS
M-Pro should not be used where there is hypersensitivity to Ciprofloxacin or to other chemotherapeutic agents of the quinolone group. M-Pro should not be prescribed to children, growing adolescents and pregnant or nursing women, as there is no evidence of its safety when used in these groups and on the basis of results from animal experiments, injury to the articular cartilage of an organism which is not fully grown cannot be completely ruled out. Animal experiments have not shown any evidence of teratogenic effects (malformations).

RESTRICTIONS TO USE
M-Pro should be used with caution in the elderly. In epileptics and in patients who have suffered from previous CNS-disorders (e.g lowered convulsion threshold, previous history convulsion, reduced cerebral blood flow, altered brain structure or stroke), M-Pro should only be used where the benefits of treatment exceed the risks, since these patients are endangered because of possible central nervous side effects.

SIDE EFFECTS
The following side effects have been observed:
- Effects on the gastro-intestinal tract:
  Nausea, diarrhoea, vomiting, digestive disorders, abdominal pain, flatulence, anorexia. The doctor should be advised about any severe or persistent diarrhoea occuring during, or after treatment. Since these symptoms could conceal a serious intestinal disorder (pseudomembranous colitis) requiring urgent treatment. In such cases, M-Pro should be discontinued and replaced by another appropriate drug (e.g. Vancomycin orally 4x250mg/day). Preparations which inhibit peristalsis are contra-indicated.
- Effects on the nervous system:
  Dizziness, headache, tiredness, insomnia, agitation, trembling, very rarely peripheral paralgesia, sweating, unsteady gait, convulsions, anxiety states, nightmares, confusion, depressions, hallucinations, impaired taste and smell, visual disturbances (e.g. double vision, colour vision). In some instances, these reactions occur after the first administration of M-Pro. In these cases M-Pro has to be discontinued and the doctor should be informed immediately.
- Hypersensitivity reactions:
  Skin reactions, e.g. rashes.
  Very rarely.
- Pruritus drug fever.
- Anaphylactic/ anaphylactoid reactions (e.g. facial, vascular, and laryngeal, oedema, dyspnoea progressing to life-threatening shock). In these cases M-Pro has to be discontinued,

medical treatment (e.g. treatment for shock) is required.
- Punctate skin haemorrhages (petechiae), blister formation with accompanying haemorrhages (haemorrhagic bullae) and small nodules (papules) with crust formation showing vascular involvement (vasculitis), Stevens-Johnson-syndrome interstitial nephritis, hepatitis, very rarely major liver disorders including hepatic necrosis.
- Effects on the cardiovascular system:
  Very rarely, tachycardia, hot flushes, migraine, fainting.
- Other:
  Very rarely, joint pains general feeling of weakness, muscular pains, tendovaginitis, mild photosensitivity, transient impairment in kidney function, including transient kidney failure, tinnitus, transitory impairment of hearing especially at high frequencies.
- Effect on blood and blood constituents:
  Eosinophilia, leucocytopenia, Leucocytosis, anaemia, very rarely thrombocytopenia, thrombocytosis, altered prothrombin levels.
- Effects on laboratory values/urine deposits:
  There may be a transient rise in the transaminase and alkaline phosphatase levels or cholestatic jaundice may occur particularly in patients with previous liver damage, transient increase in serum urea, creatinine and bilirubin levels, hyperglycaemia in individual cases, crystalluria and haematuria.

WARNING

Even when taken as prescribed, this drug can alter patients responsiveness, impairing the ability to drive or operate machinery. This is even more applicable when the drug is taken in conjunction with alcohol.

INTERACTIONS

Drug which effect the acidity of the stomach (antacids) containing aluminium hydroxide or magnesium hydroxide reduce the uptake. Consequently M-Pro should be taken either 1-2 hours before or at least 4 hours after the antacid.This restriction does not apply to antacids which do not contain aluminium or magnesium hydroxide. The simultaneous administration of M-Pro and theophyline can lead to an unwanted increase in the serum theophyline concentration; thereby producing therophylline-induced side-effects. If the concomitant administration of these two drugs is unavoidable, the serum concentration of theophylline should be checked and its dosage reduced accordingly. Animal experiments have indicated that the combination of very high doses of quinolones (gyrase inhibitors) with certain nonsteroidal anti-inflammatory drugs (e.g. fenbufen, but not acetylsalicylic acid) can lead to convulsions. However, these interactions have not been observed in patients taking M-Pro. A transient rise in the concentration of the serum creatinine was observed when M-Pro and Cyclosporin were administered simultaneously. Therefore, it is necessary to control the serum creatinine concentrations in these patients frequently (twice a week).

DOSAGE AND ADMINISTRATION

Unless prescribed otherwise, the following doses are recommended:

- Uncomplicated-infections of the lower and upper urinary tract.	2x100/125 mg/day
- Complicated infections of the urinary tract (depending on severity)	2x250-500 mg/day
- Infections of the respiratory tract (e.g. Bronchitis)	2x250-500 mg/day
- Other infections:	2x500 mg/day

In particularly severe infections e.g. recurrent infections in patients with muciviszidosis, pneumonias, infections of the abdominal cavity, bones and joints, caused by pseudomonas, staphylococcus or streptococcus pneumoniae, the daily dosage has to be increased to 2 x750 mg (oral) where the patient is not being treated intravenously.

Acute gonorrhoea and acute uncomplicated cystitis in women can be treated with a single dose of 250mg. Elderly patients should receive a dose as low as possible, taking into account the severity of the illness and the creatinine clearance. If, due to the severity of the disease or for any other reason, the patient is unable to swallow the coated tablets, it is recommended that treatment with intravenous Ciprofloxacin be initiated.

Restricted kidney and liver function:

1. Restricted kidney function.
   Creatinine clearance.
   < 20 ml/min - Serum creatinine > 3 mg/100ml: half the normal twice daily or the full normal dose once a day.
2. Restricted Kidney function + heamodialysis.
   Dosage as for 1, on dialysis after dialysis.
3. Restricted liver function.
   No dosage adjustment is required.
4. Restricted kidney and liver function levels
   Dosage adjustment as for I, possibly check M-Pro serum levels.

ADMINISTRATION

Tablets to be taken whole with a little fluid. There is no need to be taken at meal times. Absorption of the drug is accelerated if taken on an empty stomach.

ADMINISTRATION PERIOD

The treatment period depends upon the severity and the clinical course of the illness and bacteriological results. Essentially, treatment should be continued for at least 3 days after the temperature has returned to normal and / or the clinical symptoms have disappeared.

Average treatment period 1 day for acute gonorrhea, up to 7 days for infections of the kidneys, urinary tract and abdominal cavity, throughout the entire neutropenic phase in immuno-compromised patients, a maximum of 2 months for osteomyelitis and 7-14 days for all other infections.Treatment should continue for a minimum of 10 days a streptococcal infections owing to the risk of late complications.

INSTRUCTIONS

- To be sold on the prescription of a registered medical practitioner only.
- Store below 25°C.
- Protect from sunlight and moisture.
- Keep medicines out of the reach of children.

ہدایات:

صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔
دوا کو ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
دوا کو دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔

PRESENTATION

M-Pro 250 mg film coated tablets in a blister pack of 10's.
M-Pro 500 mg film coated tablets in a blister pack of 10's.

OBS

Manufactured by:
OBS Pakistan (Pvt) Ltd.
C-14, S.I.T.E., Karachi-75700.

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