速博新® 膜衣錠250，500公絲

主成分: ciprofloxacin　　廣效性抗生素　　膜衣錠

衛署藥輸字第017692號
衛署藥輸字第021062號

組成

Ciprofloxacin 250：每顆膜衣錠含291公絲（毫克）的Ciprofloxacin hydrochloride monohydrate，相當於250公絲的Ciprofloxacin。
Ciprofloxacin 500：每顆膜衣錠含582公絲（毫克）的Ciprofloxacin hydrochloride monohydrate，相當於500公絲的Ciprofloxacin。

性質

Ciprofloxacin 是一合成的廣效性抗生素。
在體外實驗中 ciprofloxacin 可以有效對抗所有的革蘭氏陰性病原菌，包括綠膿桿菌 (Pseudomonas aeruginosa)，它對革蘭氏陽性病原菌，例如葡萄球菌(staphylococci)和鏈球菌(streptococci) 也有效，而厭氧菌對其敏感度較差。
Ciprofloxacin 有快速的殺菌作用，且不只針對增生期，對休止期也有作用。
在細菌的增生期，染色體的片斷會進行纏繞及解纏繞，在這個過程中，有一個名為 DNA gyrase 的酵素扮演著決定性的角色。Ciprofloxacin 會抑制 DNA gyrase，進而阻止細菌進行新陳代謝，因為細菌的染色體無法再提供生命合成的訊息。
Ciprofloxacin 的抗藥性發展得很慢，且是逐步產生的（多步驟型態）。
藉由質體媒介而對 β-lactam 類抗生素、aminoglycosides、及四環素 (tetracyclines)，產生抗藥性的情形在 ciprofloxacin 上還未被發現。在臨床上值得注意的是攜帶質體的細菌對 ciprofloxacin 也是相當敏感。
Ciprofloxacin 因為其特殊的作用模式，所以與其他重要但化學構造不同的有效物質，如 β-lactam 類抗生素、aminoglycosides、四環素 (tetracyclines)、巨環素(macrolide)、peptide 抗生素、sulphonamides、trimethoprim 或 nitrofuran 的衍生物，並不會產生平行的抗藥性。在 ciprofloxacin 的適應範圍下，對上述抗生素有抗藥性的病原菌，ciprofloxacin 依然是完全有效的。
平行抗藥性會發生在同樣是 gyrase 抑制劑的藥物，然而因為多數的病原菌對 ciprofloxacin 原本的敏感度就高，所以較少提及此藥的平行抗藥性。因此對其他的 gyrase 抑制劑已有抗藥性的病原菌，通常ciprofloxacin 依然對其有效。
由於 ciprofloxacin 的化學構造，它對會形成 β-lactamase 的細菌是完全有效的。
Ciprofloxacin 可以與其他抗生素併用。以具敏感度的病原菌做體外實驗指出，ciprofloxacin 和 β-lactam 類抗生素及 aminoglycosides 併用只有基本的加成或一樣的效果；在療效上協同作用的增強是較少的，而互抵的作用非常少。

可以併用的藥物包括：
治療假單胞菌 (pseudomonas)：azlocillin、ceftazidime
治療鏈球菌 (streptococci)：mezlocillin、azlocillin、其他有效的 β-lactam 抗生素
治療葡萄球菌 (staphylococci)：β-lactam抗生素，尤其是isoxazolylpenicillins、vancomycin
治療厭氧菌 (anaerobes)：metronidazole、clindamycin

適應症

對 ciprofloxacin 有感受性之細菌所引起之呼吸道感染、中耳炎、竇炎、眼感染、腎臟及泌尿道感染（包括淋病）、腹部感染（包括腹膜炎）、皮膚及軟組織感染、骨髓炎、關節感染、菌血症。
[說明]
- 呼吸道的感染
- 因肺炎雙球菌 (Pneumococcus) 引起肺炎之門診病人，ciprofloxacin 不應用為第一線治療用藥。而對於治療由克雷白桿菌屬 (Klebsiella)、大腸桿菌屬 (Enterobacter)、變形桿菌屬 (Proteus)、大腸桿菌 (E. coli)、假單胞菌屬 (Pseudomonas)、嗜血桿菌屬 (Haemophilus)、Branhamella、Legionella、及葡萄球菌屬 (Staphylococcus) 所引起的肺炎，ciprofloxacin 則作為合適的治療用藥。
- 中耳（中耳炎）、副鼻竇（鼻竇炎）的感染，尤其是由包括假單胞菌屬 (Pseudomonas) 在內的革蘭氏陰性菌，或葡萄球菌屬 (Staphylococcus) 所引起。
- 眼部的感染
- 腎和/或泌尿道的感染
- 生殖器官的感染，包括子宮附屬器炎、淋病、前列腺炎
- 腹腔的感染（例如腸胃道、膽管的感染、腹膜炎）
- 皮膚及軟組織的感染
- 骨頭及關節的感染
- 敗血症
- 免疫系統衰弱的病人（如接受免疫抑制治療或處於嗜中性白血球減少狀態的病人）已受感染或具高度被感染危險時的預防
- 對於免疫抑制的病人的選擇性腸內淨化
- 根據體外試驗指出，下列病原菌對 ciprofloxacin 具感受性：大腸桿菌 (E. coli)、志賀桿菌屬 (Shigella)、沙門桿菌 (Salmonella)、Citrobacter、克雷白桿菌屬 (Klebsiella)、大腸桿菌屬 (Enterobater)、鋸桿菌屬 (Serratia)、Hafnia、Edwardsiella、變形桿菌屬（Proteus、indole 陽性及indole 陰性）、Providencia、Morganella、Yersinia；弧菌類 (Vibro)、產氣單胞菌屬(Ameromonas)、Plesiomonas、巴斯德桿菌屬(Pasteurella)、嗜血桿菌屬 (Haemophilus)、Campylobacter、假單胞菌屬 (Pseudomonas)、Legionella、奈塞氏球菌屬 (Neisseria)、Moraxella、Acinetobacter、布氏桿菌屬 (Brucella)；葡萄球菌屬(Staphylococcus)、Listeria、棒球桿菌屬(Corynebacterium)、披衣菌 (Chlamydia)。
- 下列菌種顯現不同的感受性：
  Gardnerella、黃質菌屬 (Flavobacterium)、產鹼桿菌屬 (Alcaligenes)、無乳鏈球菌 (Streptococcus agalactiae)、Enterococcus faecalis、釀膿鏈球菌 (Streptococcus pyogenes)、肺炎鏈球菌 (Streptococcus pneumoniae)、草綠色鏈球菌 (Viridans group Streptococci)、Mycopalsma hominis、結核桿菌 (Mycobacterium tuberculosis)、Mycobacterium fortuitum。
- 下列菌種通常具抗藥性：
  Enterococcus faecium、Ureaplasma urealyticum、星形土壤絲菌 (Nocardia asteroids)。
  除少許例外，厭氧菌對 ciprofloxacin 通常具中等敏感度（如Peptococcus，Peptostreptococcus），或具抗藥性，如 Bacteroides。
- Ciprofloxacin對梅毒螺旋體 (Treponema pallidum) 無效。

劑量與用法《本藥須由醫師處方使用》

成人
除非有其他處方，建議劑量如下：

	膜衣錠
呼吸道感染 （根據嚴重度及感染病菌）	2×250 - 500公絲
泌尿道感染： - 急性、非併發型 - 女性膀胱炎（停經前） - 併發型	2×125公絲到1-2×250公絲 單一劑量250公絲 2×250 - 500公絲
淋病 - 外生殖器 - 急性、非併發型	2×125公絲 單一劑量250公絲
腹瀉	1 - 2×500公絲
其他感染（見適應症）	2×500公絲
特別嚴重、會威脅生命的感染。 例如 - 鏈球菌感染引起的肺炎 - 囊腫性纖維化的復發感染 - 骨頭及關節的感染 - 敗血症 - 腹膜炎 特別是有假單胞菌屬 (Pseudomonas)、葡萄球菌屬 (Staphylococcus)和鏈球菌 (Streptococcus)存在時。	2×750公絲

給藥方法
錠劑應整顆和少量水一起吞服。
飯前或飯後皆可，如果空腹服用，活性成分吸收較快。因為這樣，錠劑或懸浮液不可和乳製品或礦物質含量高的飲料（例如牛奶、優格、加鈣柳橙汁）併用。但是，作為正餐中一部份的膳食鈣並不會明顯影響Ciprofloxacin吸收。
若病人因疾病嚴重或其他原因無法服用錠劑，建議可以一開始時以靜脈輸注 ciprofloxacin 來治療，再以口服錠劑來持續治療。

治療期
治療期間的長短由疾病的嚴重程度及臨床和細菌生長的週期決定。在發燒或臨床症狀消失後須持續給藥至少三天。平均治療期為：
- 急性、非併發型淋病及膀胱炎為1天
- 腎、泌尿道和腹腔感染可高達7天
- 身體防禦力弱的病人在整個嗜中性白血球減少的期間都要用藥
- 骨髓炎病人最多2個月
- 其它感染為7 - 14天

在鏈球菌的感染時，因會有續發併發症的危險，所以治療必須持續至少10天。
由披衣菌所引起的感染，治療也必須持續至少10天。

老年人：年老的病患應依其病情嚴重性及肌氨酸酐(creatinine)清除率給予最低的藥量。
小孩：禁止使用。
腎及肝功能受損
1. 腎功能受損
1.1 當creatinine清除率在31到60 ml/min/1.73m²或血漿中creatinine 的濃度在1.4到1.9 mg/100ml時，每日最大口服劑量為一天1000公絲。
1.2 當creatinine清除率少於或等於30 ml/min/1.73m²或血漿中creatinine的濃度等於或高於2.0 mg/100ml 時，每日最大口服劑量為一天500公絲。
2. 腎功能受損且須血液透析劑量如1.2所述；在透析當日，於透析完再給藥。
3. 腎功能受損且進行連續性腹膜透析之門診病人一顆 500 公絲的 ciprofloxacin 膜衣錠或二顆 250 公絲的 ciprofloxacin 膜衣錠。
4. 肝功能受損
   不須調整劑量。
5. 腎及肝功能受損
   劑量調整如1.1和1.2所述。

配伍禁忌

Ciprofloxacin 不可使用於對 ciprofloxacin 或其他quinolone 類藥物會過敏的病人。

Ciprofloxacin 不可使用於小孩、青少年。因為沒有這類病患群的用藥安全經驗，且基於動物實驗的結果，它有可能對尚未成熟生物的關節軟骨造成傷害。

警語及注意事項

腸胃系統

在治療期或治療後有嚴重且持續性的腹瀉，必須請教醫生，因為在這個症狀背後，可能隱藏著嚴重的腸道疾病（威脅生命的偽膜性結腸炎，有可能致死），需立即治療。在這種情況下，必須停用 ciprofloxacin 並給予適當的治療（如 vancomycin 口服每天四次，每次250公絲），禁用抑制蠕動的藥物。轉氨酵素 (transaminases)、鹼性磷酸鹽酵素 (alkaline phosphatase)、或膽汁鬱滯性黃疸 (cholestatic jaundice) 會暫時升高，特別是之前就有肝受損的病人。

神經系統

對於癲癇病人及曾患有中樞神經失調的病人（例如痙攣閾值偏低、曾有痙攣的病史、腦部血流減少、腦部結構改變或中風），ciprofloxacin 應只用在治療效益大於危險性的情況下，因為這些病人會因為可能出現的中樞神經副作用而導致危險。在某些例子中，第一次給予 ciprofloxacin 後就發生中樞神經的反應。在少數的情況，抑鬱或精神錯亂可能會演變成自我傷害的行為，在這些情況下，ciprofloxacin 必須停藥，並立刻通知醫生。

過敏反應

在某些例子中，第一次給予 ciprofloxacin 後發生過敏反應，須立刻通知醫生。

在極少數的情況下，過敏性及類過敏性反應會變成具生命危險性的休克。在這些情況下，ciprofloxacin 必須停藥，並進行藥物治療（如休克的治療）。

肌肉骨骼系統

若有任何肌腱炎的跡象（如疼痛性腫脹），應停用 ciprofloxacin，避免身體上的運動，並通知醫生。

肌腱斷裂（主要是阿基里斯腱）常發生在之前曾使用醣質類固醇治療的老年人。

皮膚與附屬器官

Ciprofloxacin 會產生光敏感反應。服用 ciprofloxacin 的病患應避免暴露於過量的陽光及紫外線下。若有光過敏作用（如像曬傷般的皮膚反應）產生，須停止給藥。

駕駛及操作機械的能力

即使遵照醫囑正確地用藥，此藥仍會影響反應的速度以致於開車或操作機械的能力會有損害，尤其與酒精併用時更易發生。

交互作用

Ciprofloxacin（口服）和含多價陽離子的藥物、礦物質補充劑（例如鈣、鎂、鋁及鐵劑）、sucralfate、制酸劑或高緩衝性藥物（例如抗反轉錄病毒藥物，antiretroviral）等含鎂、鋁或鈣的藥物併用時會降低 Ciprofloxacin 的吸收，因此 Ciprofloxacin 應在這些製劑服用前 1-2 小時或服用後至少 4 小時才可服用。

H2 接受體阻斷劑類的制酸劑不受此限。

必須避免乳製品或礦物質含量高的飲料（例如牛奶、優格、加鈣柳橙汁）和 ciprofloxacin 併用，因為 ciprofloxacin 的吸收可能會降低。但是，作為正餐中一部份的膳食鈣並不會明顯影響 ciprofloxacin 的吸收。

Ciprofloxacin 和 omeprazole 併服會導致 ciprofloxacin 血中最大濃度及曲線下面積輕微地降低。

Ciprofloxacin 和 theophylline 一起服用會使 theophylline 的血中濃度增加，導致 theophylline 引發的副作用；在極少數的情況下，這些副作用會造成生命危險或致命的。如果無法避免併用此兩種藥物，應監測血中 theophylline 濃度且適當減少 theophylline 的劑量。

動物研究顯示非常高劑量的 quinolones 藥物（gyrase 抑制劑）和某些非固醇類抗發炎藥物（acetylsalicylic acid 除外）併用會引起痙攣。

Ciprofloxacin 和 cyclosporin 併用會造成血中肌氨酸酐濃度的暫時性升高。因此，需時常（一星期二次）控制這類病患血中肌氨酸酐的濃度。

併用 Ciprofloxacin 和 warfarin 可能會加強 warfarin 的作用。

在特殊的病例中，ciprofloxacin 與 glibenclamide 一起服用會加強 glibenclamide 的作用（低血糖）。

Probenecid 會干擾 Ciprofloxacin 的腎排除，所以併用 Ciprofloxacin和 probenecid 會增加 Ciprofloxacin 的血中濃度。

Methotrexate 在腎小管的輸送可能因併服 ciprofloxacin 而受到抑制，導致 methotrexate 血漿濃度增加，這可能增加 methotrexate 所引起毒性反應的危險性，因此，使用 methotrexate 治療的病人，當要併服 ciprofloxacin 時，必須小心監測。

Metoclopramide 會加速 Ciprofloxacin 口服的吸收而使其在較短的時間內達到最大血中濃度，但其對 Ciprofloxacin 的生體可用率沒有影響。

懷孕與授乳

孕婦及哺乳的母親不能服用 ciprofloxacin，因為沒有這些類患群使的用藥安全經驗，且基於動物實驗的結果，它有可能對尚未成熟生物的關節軟骨造成傷害。

動物實驗至今尚未有致畸胎（畸形）的證據。

副作用

根據 ciprofloxacin（口服、注射）的所有臨床研究，將其最常見的副作用依身體系統及副作用名稱分類（n=41151位病人）

身體系統	副作用
發生頻率 ≧ 1% <10%	
消化系統:	噁心、腹瀉
皮膚與附屬器官:	紅疹
發生頻率 ≧ 0.1% <1%	
全身:	腹部疼痛、念珠菌病 (moniliasis)、無力（感到全身虛弱、疲倦）
心血管系統:	(血栓) 靜脈炎
消化系統:	SGOT升高、SGPT升高、嘔吐、消化不良、肝功能指數異常、鹼性磷酸鹽酵素升高、厭食、脹氣、血中膽紅素過高 (bilirubinemia)
血液及淋巴系統:	嗜伊紅血球增多 (eosinophilia)、白血球減少 (leukopenia)
代謝及營養失調:	creatinine 增加、血氨（尿素）增加
肌肉骨骼系統:	關節痛 (arthralgia)
神經系統:	頭痛、暈眩、失眠、易怒、精神混亂
皮膚與附屬器官:	搔癢、斑丘疹 (maculopapular)、蕁麻疹 (urticaria)
感覺異常:	味覺失常
發生頻率 ≧ 0.01% <0.1%	
全身:	疼痛、極度疼痛、背痛、胸痛
心血管系統:	心跳加速、偏頭痛、暈厥（昏倒）、血管擴張（熱潮紅）、低血壓
消化系統:	念珠菌病（口腔）、黃疸、膽汁鬱滯性黃疸、偽膜性結腸炎
血液及淋巴系統:	貧血、白血球減少（顆粒性血球減少）、白血球增多 (leucocytosis)、凝血酵素原 (prothrombin)數值改變、血小板減少 (thrombocytopenia)、血小板增多 (thrombocytosis)
過敏反應:	過敏反應、藥物熱、類過敏性休克（過敏性休克）反應
代謝及營養失調:	水腫（周邊、血管、臉）、血糖過高
肌肉骨骼系統:	肌肉酸痛、關節失常（關節腫大）
神經系統:	幻想、出汗、感覺異常（周邊感覺異常）、焦慮、不正常的做夢（惡夢）、抑鬱、顫抖、痙攣、感覺遲鈍
呼吸系統:	呼吸困難、喉部水腫
皮膚與附屬器官:	光敏感反應
感覺異常:	耳鳴、短暫的失聰（尤其在給藥頻率高時）、視覺異常（視覺紊亂）、複視、色幻覺 (chromatopsia)、味覺喪失
泌尿生殖系統:	急性腎衰竭、腎功能異常、陰道念珠菌病、血尿、結晶尿、間質性腎炎 (interstital nephritis)
發生頻率 <0.01%	
心血管系統:	血管炎（瘀斑、出血性的水泡、小結 (papules)、結痂 (crust)）
消化系統:	念珠菌病（腸胃道）、肝炎
血液及淋巴系統:	溶血性貧血
過敏反應:	休克（過敏性休克；有生命危險的）、搔癢、紅疹
代謝及營養失調:	澱粉酵素增加、脂肪分解酵素增加
肌肉骨骼系統:	肌無力
神經系統:	大發作癲癇、步態不穩
皮膚及附屬器官:	瘀斑 (petechia)、多處紅疹（輕微）、結節性紅斑 (erythema nodosum)

依據用藥病人持續的報告，將其最常見之副作用依身體系統和副作用名稱計算（n=7790報告病例）

發生頻率 < 0.01%	
消化系統:	肝壞死（只有很少的機會會轉變成有生命危險的肝衰竭）、會威脅到生命的偽膜性結腸炎，且有死亡的可能、胰臟炎
血液和淋巴系統:	瘀斑（皮膚出血）、全血球減少 (pancytopenia)、顆粒性血球減少 (agranulocytosis)、全血球減少 (pancytopenia)（有生命危險的）、骨髓功能降低（有生命危險的）
肌肉骨骼系統:	肌腱炎（主要是阿基理斯 (achillo) 肌腱炎）、部份或全部的肌腱斷裂（主要是阿基理斯 (Achilles)肌腱）、重症肌無力的惡化
神經系統:	精神錯亂、顱內高血壓、運動失調、感覺過敏、壓力過高、抽搐
皮膚和附屬器官:	Stevens - Johnson 症狀、表皮壞死 (Lyell症狀)、發疹
過敏反應:	類血漿疾病反應 (serum sickness like reaction)
感覺異常:	嗅覺障礙 (parosmia)、嗅覺缺失（通常在停藥後恢復）

過量

在一些急性口服過量的病例中，曾有可逆轉腎毒性的報告。因此，除了一般急救措施外，還建議監測腎功能，並且給予含鎂、鈣的制酸劑以減少 ciprofoxacin 的吸收。

只有一小部份的 ciprofloxacin (<10%) 在血液透析及腹膜透析後會從身體內被移除。

注意

藥物應置於小孩拿不到的地方。

過期後不可繼續使用。

包裝

4 - 1000錠鋁箔盒裝。（PVDC/PVC-Al及PP-Al）

製造廠：Bayer HealthCare AG　德國拜耳藥廠
廠　址：D-51368 Leverkusen, Germany
藥　商：台灣拜耳股份有限公司
地　址：台北市信義路五段7號54樓
電　話：(02)81011000
網　址：www.bayer-pharma.com.tw
Ciproxin 250/500 film-coated tablets / OE19 / TW01 / 072003

Ciproxin® 250, 500, film-coated tablets

Active ingredient: ciprofloxacin

Broad-spectrum antibiotic
Film-coated tablets

Composition
Ciproxin 250: 1 film-coated tablet contains 291 mg ciprofloxacin hydrochloride monohydrate, corresponding to 250 mg ciprofloxacin.
Ciproxin 500: 1 film-coated tablet contains 582 mg ciprofloxacin hydrochloride monohydrate, corresponding to 500 mg ciprofloxacin.

Properties
Ciprofloxacin is a synthetic broad spectrum antibacterial agent.
Ciprofloxacin is effective in-vitro against virtually all gram-negative pathogens, including Pseudomonas aeruginosa. It is also effective against gram-positives such as staphylococci and streptococci. Anaerobes are generally less susceptible.
Ciprofloxacin has a rapid bactericidal action, not only in the proliferation phase but also in the resting phase.
During the proliferation phase of a bacterium a segmental twisting and untwisting of the chromosomes take place. An enzyme called DNA gyrase plays a decisive part in this process. Ciprofloxacin inhibits this DNA gyrase in a way that arrests the bacterial metabolism, since vital information can no longer be read from the bacterial chromosome.
Resistance to ciprofloxacin develops slowly and in stages (multiple-step type).
Plasmid-mediated resistance development of the kind that occurs with β-lactam antibiotics, aminoglycosides, and tetracyclines has not been observed with ciprofloxacin. It is of clinical interest that plasmid-carrying bacteria are also completely sensitive to ciprofloxacin.
On account of its special mode of action, ciprofloxacin does not suffer from general parallel resistance to other important, chemically different, active substance groups, such as β-lactam antibiotics, aminoglycosides, tetracyclines, macrolide or peptide antibiotics, sulphonamides, trimethoprim or nitrofuran derivatives. In its indication area ciprofloxacin remains completely effective on pathogens resistant to the above-mentioned groups of antibiotics.
Parallel resistance is observed within the group of gyrase inhibitors. However, because of the high primary sensitivity to ciprofloxacin shown by most organisms parallel resistance is less pronounced with this drug. Ciprofloxacin is thus often still effective on pathogens that are already resistant to the less effective gyrase inhibitors.
Because of its chemical structure ciprofloxacin is completely effective on β-lactamase-forming bacteria.
Ciprofloxacin can be used in combination with another antibiotic. In-vitro studies with usually sensitive pathogens, carried out using ciprofloxacin in combination with β-lactam antibiotics and aminoglycosides, have shown primarily additive or indifferent effects; synergistic increases in efficacy were relatively rare and antagonistic effects very rare.
Possible combination drugs include:

for pseudomonas:	*azlocillin, ceftazidime*
for streptococci:	mezlocillin, azlocillin, other effective β-lactam antibiotics
for staphylococci:	β-lactam antibiotics, particularly isoxazolyl-penicillins, vancomycin
for anaerobes:	metronidazole, clindamycin

Indications
UNCOMPLICATED AND COMPLICATED INFECTIONS CAUSED BY CIPROFLOXACIN SENSITIVE PATHOGENS:
- Infections of the respiratory tract
- In the treatment of outpatients with pneumonia due to Pneumococcus ciprofloxacin should not be used as a first choice of drug. Ciprofloxacin can be regarded as an advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, E. coli, Pseudomonas, Haemophilus, Branhamella, Legionella, and Staphylococcus.
- Infections of the middle ear (otitis media), of the paranasal sinuses (sinusitis), especially if these are caused by gram negative organisms including Pseudomonas or by Staphylococcus.
- Infections of the eyes
- Infections of the kidneys and/or the efferent urinary tract
- Infections of the genital organs, including adnexitis, gonorrhoea, prostatitis
- Infections of the abdominal cavity (e.g. infections of the gastrointestinal tract or of the biliary tract, peritonitis)
- Infections of the skin and soft tissue
- Infections of the bones and joints
- Sepsis
- Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or have neutropenia)
- Selective intestinal decontamination in immunosuppressed patients
- According to in-vitro investigations, the following pathogens 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, Acinetobacter, Brucella; Staphylococcus, Listeria, Corynebacterium, Chlamydia.
- The following show varying degrees of sensitivity:
  Gardnerella, Flavobacterium, Alcaligenes, Streptococcus agalactiae, Enterococcus faecalis, Streptococcus pyogenes, Streptococcus pneumoniae, Viridans group streptococci, Mycoplasma hominis, Mycobacterium tuberculosis, and Mycobacterium fortuitum.
- The following are usually resistant:
  Enterococcus faecium, Ureaplasma urealyticum, Nocardia asteroides.
- With a few exceptions anaerobes are moderately sensitive e.g. Peptococcus, Peptostreptococcus to resistant e.g.Bacteroides.
- Ciprofloxacin is ineffective against Treponema pallidum

Posology and method of administration
Adults
Unless otherwise prescribed, the following guideline doses are recommended:

	Tablets
Respiratory tract infection (according to severity and organism)	2 x 250-500 mg
Urinary tract infections: - acute, uncomplicated - cystitis in women(before menopause) - complicated	 2 x 125 mg to 1-2 x 250 mg single dose 250 mg 2 x 250-500 mg
Gonorrhea - extragenital - acute, uncomplicated	 2 x 125 mg single dose 250 mg
Diarrhea	1-2 x 500 mg
Other infections (see Indications)	2 x 500 mg
Particularly severe, life threatening infections, i.e. - Streptococcal pneumonia - Recurrent infections in cystic fibrosis - Bone and joint infections - Septicemia - Peritonitis In particular when Pseudomonas, Staphylococcus or Streptococcus is present	2 x 750 mg

Method of administration
The tablets are swallowed whole with a small amount of fluid.
They can be taken independent of mealtimes.
If they are taken on an empty stomach, the active substance is absorbed more rapidly. In this case, tablets or suspension should not be taken concurrently with dairy products or with mineral fortified drinks alone (e.g. milk, yoghurt, calcium fortified orange juice). However, dietary calcium as part of a meal does not significantly affect ciprofloxacin absorption.
If the patient is unable to take tablets, because of the severity of the illness or for other reasons, it is recommended to commence the therapy with an intravenous form of ciprofloxacin. After intravenous administration the treatment can be continued orally.
Duration of treatment
The duration of treatment depends on the severity of the illness and on the clinical and bacteriological course. It is essential to continue therapy for at least 3 days after disappearance of the fever or of the clinical symptoms. Mean duration of treatment:
- 1 day for acute uncomplicated gonorrhoea and cystitis,
- up to 7 days for infections of the kidneys, urinary tract, and abdominal cavity,
- over the entire period of the neutropenic phase in patients with weakened body defences,
- a maximum of 2 months in osteomyelitis,
- 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.
Infections caused by Chlamydia should also be treated for a minimum of 10 days.
Elderly: Elderly patients should receive a dose as low as possible depending on the severity of their illness and the creatinine clearance.
Children: contraindicated
Renal and hepatic impairment
1. Impaired renal function
1.1 Where creatinine clearance is between 31 and 60 ml/min/1.73m² or where the serum creatinine concentration is between 1.4 and 1.9 mg/100 ml the maximum daily dose should be 1000 mg per day for oral administration.
1.2 Where creatinine clearance is equal or is less than 30 ml/min/1.73m² or where the serum creatinine concentration is equal or higher than 2.0 mg/100 ml the maximum daily dose should be 500 mg per day for oral administration.
2. Impaired renal function + haemodialysis
   Dose as in 1.2; on dialysis days after dialysis.
3. Impaired renal function + CAPD
   Administration of ciprofloxacin film coated tablets as 1 x 500 mg film coated tab let (or 2 x 250 mg film coated tablets).
4. Impaired liver function
   No dose adjustment is required.
5. Impaired renal and liver function
   Dose adjustment as in 1.1 and 1.2

Contraindication
Ciprofloxacin must not be used in cases of hypersensitivity to ciprofloxacin or other quinolone chemotherapeutics.
Ciprofloxacin must not be prescribed for children, adolescents, since there is no experience on the drug's safety in these patient groups and since, on the basis of animal studies, it is not entirely improbable that the drug could cause damage to articular cartilage in the immature organism.

Special warnings and precautions for use
Gastrointestinal system
In the event of severe and persistent diarrhoea during or after treatment a doctor must be consulted, since this symptom can hide a serious intestinal disease (life threatening pseudomembranous colitis with possible fatal outcome), requiring immediate treatment. In such cases Ciprofloxacin must be discontinued and appropriate therapy initiated (e.g. vancomycin, orally, 4 x 250 mg/day). Drugs that inhibit peristalsis are contraindicated.
There can be a temporary increase in transaminases, alkaline phosphatase or cholestatic jaundice, especially in patients with previous liver damage
Nervous system
In epileptics and in patients who have suffered from previous CNS-disorders (e.g. lowered convulsion threshold, previous history of convulsion, reduced cerebral blood flow, altered brain structure or stroke),

ciprofloxacin should only be used where the benefits of treatment exceed the risks, since these patients are endangered because of possible central-nervous side effects.
In some instances the CNS reactions occurred after the first administration of Ciprofloxacin already. In rare cases depression or psychosis can progress to self endangering behaviour. In these cases Ciprofloxacin has to be discontinued and the doctor should be informed immediately.

Hypersensitivity
In some instances, the hypersensitivity and allergic reactions already occurred after the first administration and the doctor should be informed immediately.
Anaphylactic/anaphylactoid reactions in very rare instances can progress to a life threatening shock, in some instances after the first administration. In these cases Ciprofloxacin has to be discontinued, medical treatment (e.g. treatment for shock) is required.

Musculo-skeletal system
At any sign of tendinitis (e.g. painfull swelling) the administration of Ciprofloxacin should be discontinued, physical exercises be avoided, and a physician be consulted.
Tendon rupture (predominantly achilles tendon) has been reported predominantly in the elderly on prior treatment with glucocorticoids.

Skin and appendages
Ciprofloxacin has been shown to produce photosensitivity reactions. Patients taking Ciprofloxacin should avoid direct exposure to excessive sunlight or UV-light. Therapy should be discontinued if photosensitation (i.e. sunburn-like skin reactions) occurs.

Ability to drive and use machines
Even when the drug is taken exactly as prescribed, it can affect the speed of reaction to such an extent that the ability to drive or to operate machinery is impaired. This applies particularly in combination with alcohol.

Interactions
The simultaneous administration of ciprofloxacin (oral) and multivalent cation-containing drugs and mineral supplements (e.g. calcium, magnesium, aluminium, iron), sucralfate or antacids and highly buffered drugs (e.g. anti retrovirals), containing magnesium, aluminium or calcium reduce the absorption of ciprofloxacin. Consequently, ciprofloxacin should be administered either 1-2 hours before, or at least 4 hours after these preparations.
This restriction does not apply to antacids belonging to the class of H_2 receptor blockers.
The concurrent administration of dairy products or mineral fortified drinks alone (e.g. milk, yoghurt, calcium fortified orange juice) and ciprofloxacin should be avoided because absorption of ciprofloxacin may be reduced. Dietary calcium as part of a meal, however, does not significantly affect absorption.
Concomitant administration of ciprofloxacin and omeprazole results in a slight reduction of C_{max} and AUC of ciprofloxacin.
Concurrent administration of ciprofloxacin and theophylline can cause an undesirable increase in the serum theophylline concentration. This can lead to theophylline-induced side effects; in very rare cases these side effects can be life threatening or fatal. If concurrent use of the two products is unavoidable, the serum theophylline concentration should therefore be checked and the theophylline dose appropriately reduced.
Animal studies have shown that the combination of very high doses of quinolones (gyrase inhibitors) and certain non-steroidal anti-inflammatory agents (but not acetylsalicylic acid) can provoke convulsions.
A transient rise in the concentration of serum creatinine was observed when ciprofloxacin and cyclosporin were administered simultaneously. Therefore, it is necessary to control the serum creatinine concentrations in these patients frequently (twice a week).
The simultaneous administration of ciprofloxacin and warfarin may intensify the action of warfarin
In particular cases, concurrent administration of ciprofloxacin and glibenclamide can intensify the action of glibenclamide (hypoglycaemia)
Probenecid interferes with renal secretion of ciprofloxacin. Co-administration of probenecid and ciprofloxacin increases the ciprofloxacin serum concentrations.
Renal tubular transport of methotrexate may be inhibited by concomitant administration of ciprofloxacin potentially leading to increased plasma levels of methotrexate. This might increase the risk of methotrexate associated toxic reactions. Therefore, patients under methotrexate therapy should be carefully monitored when concomitant ciprofloxacin therapy is indicated.
Metoclopramide accelerates the absorption of ciprofloxacin (oral) resulting in a shorter time to reach maximum plasma concentrations. No effect was seen on the bioavailability of ciprofloxacin.

Pregnancy and lactation
Ciprofloxacin must not be prescribed for pregnant women, or nursing mothers, since there is no experience on the drug's safety in these patient groups and since, on the basis of animal studies, it is not entirely improbable that the drug could cause damage to articular cartilage in the immature organism.
Animal studies have not shown any evidence of teratogenic effects (malformations).

Undesirable effects
The most common Adverse Reactions based on all clinical studies with ciprofloxacin (oral, parenteral) sorted by body system and terms (n = 41151 patients)

BODY SYSTEM	**Adverse Drug Reactions**
Incidence of frequency ≥ 1 % < 10 %	
Digestive system:	nausea, diarrhoea
Skin and appendages:	rash
Incidence of frequency ≥ 0.1 % < 1 %	
Body as a whole:	abdominal pain, moniliasis, asthenia (general feeling of weakness, tiredness)
Cardiovascular system:	(thrombo)-phlebitis
Digestive system:	SGOT increased, SGPT increased, vomiting, dyspepsia, abnormal liver functiontest, alkaline phosphatase increased, anorexia, flatulence, bilirubinemia
Hemic and lymphatic system:	eosinophilia, leukopenia
Metabolic and nutritional disorder:	creatinin increased, BUN (urea) increased
Musculo Skeletal system:	arthralgia (joint pain)
Nervous system:	headache, dizziness, insomnia, agitation, confusion
Skin and appendages:	pruritus, maculopapular rash, urticaria
Special senses:	taste perversion
Incidence of frequency ≥ 0.01 % < 0.1 %	
Body as a whole:	pain, pain in extremities, back pain, chest pain
Cardiovascular system:	tachycardia, migraine, syncope (fainting) asodilatation (hot flushes), hypotension
Digestive system:	moniliasis (oral), jaundice, cholestatic jaundice, pseudomembranous colitis
Hemic and lymphatic system:	anaemia, leucopenia (granulocytopenia), leucocytosis, altered prothrombin values, thrombocytopenia, thrombocytemia (thrombocytosis)
Hypersensitivity:	allergic reaction, drug fever, anaphylactoid (anaphylactic) reaction
Metabolic disorders:	edema (peripheral, vascular, face), hyperglycemia
Musculo-Skeletal system:	myalgia (muscular pain), joint disorder (joint swelling)
Nervous system:	hallucination, sweating, paresthesia (peripheral paralgesia), anxiety, abnormal dreams (nightmares), depression, tremor (trembling), convulsion, hypesthesia
Respiratory system:	dyspnea, larynx edema
Skin and appendages:	photosensitivity reaction
Special senses:	tinnitus, transitory deafness (especially at high frequencies), abnormal vision (visual disturbances), diplopia, chromatopsia, taste loss (impaired taste)
Urogenital system:	acute kidney failure, kidney function abnormal, vaginal moniliasis, hematuria, crystalluria, nephritis interstitial
Incidence of frequency < 0.01 %	
Cardiovascular system:	vasculitis (petechiae, haemorrhagic bullae, papules, crust formation)
Digestive system:	moniliasis (gastrointestinal), hepatitis,
Hemic and lymphatic system:	hemolytic anaemia
Hypersensitivity:	shock (anaphylactic; life threatening), pruritic rash
Metabolic and nutritional disorder:	amylase increased, lipase increased
Musculo-sclereteral system:	myasthenia
Nervous system:	grand mal convulsion, abnormal (unsteady) gait
Skin and appendages:	petechia, erythema multiforme (minor), erythema nodosum

The most common Adverse Reactions based on spontaneous reports sorted by body system and terms calculated on patient exposure (n = 7790 reported cases)

Incidence of frequency < 0.01 %	
Digestive system:	liver necrosis (very rarely progressing to life-threatening hepatic failure), *life threatening* pseudomembranous colitis with possible fatal outcome, pancreatitis
Hemic and lymphatic system:	petechia (punctuate skin hemorrhages), pancytopenia, agranulocytosis, pancytopenia (life-threatening), marrow depression (life-threatening)
Musculo-Skeletal system:	tendinitis (predominantly achillo tendinitis); partial or complete tendon rupture (predominantly achilles tendon), exacerbation of symptoms of myasthenia gravis
Nervous system:	psychosis, intracranial hypertension, ataxia, hyperesthesia, hypertonia, twitching
Skin and appendages:	Stevens-Johnson-Syndrome, epidermal necrolysis (Lyell-Syndrome), fixed eruption
Hypersensitivity:	serum sickness like reaction
Special senses:	parosmia (impaired smell), anosmia (usually reversible upon discontinuation)

Overdose
In the event of acute, excessive oral overdosage, reversible renal toxicity has been reported in some cases.
Therefore, apart from routine emergency measures, it is recommended to monitor renal function and to administer Mg- or Ca-containing antacids which reduce the absorption of ciprofloxacin.
Only a small amount of ciprofloxacin (< 10 %) is removed from the body after haemodialysis or peritoneal dialysis.

Keep drugs out of reach of children.

Ciprobay tablets must not be used after the expiry date.

Presentation
4 - 1000's per box

Bayer HealthCare AG, D-51368 Leverkusen, Germany

Ciproxin 250, 500 film-coated tablets / OE19 / TW01 / 072003