Ciprofloxacin

Section: 6. Anti-infective medicines > 6.2. Antibacterials > 6.2.2. Watch group antibiotics

ATC codes: J01MA02

Indication	Inflammatory or other diseases of prostate ICD11 code: GA91.Z
INN	Ciprofloxacin
Medicine type	Chemical agent
Antibiotic groups	WATCH
List type	Core
Formulations	**Oral > Solid > dosage form:** 250 mg (as hydrochloride) ; 500 mg (as hydrochloride)
EML status history	First added in 2017 (TRS 1006) Changed in 2021 (TRS 1035)
Sex	Male
Age	Adolescents and adults
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Patents have expired in most jurisdictions Read more about patents.
Wikipedia	Ciprofloxacin
DrugBank	Ciprofloxacin

Expert Committee recommendation

The Expert Committee recommended the addition of the new strength formulations of amoxicillin, cefalexin, ceftriaxone, ciprofloxacin, clindamycin, phenoxymethylpenicillin and vancomycin to the existing listings of these medicines on the EML for the indications for which they are proposed. The Committee noted that the proposed strength formulations are higher than those currently included on the Model List, and are appropriate and aligned to meet recommended doses for treatment of adults, with the advantages of a reduced pill burden in the case of oral formulations, and facilitating a simplified and safer dose administration in the case of intravenous formulations.

Background

The application requested the inclusion of new higher strengths of the following antibiotics on the EML to better align with the dosing needs of adults: Amoxicillin: solid oral dosage form 1 g Cefalexin: solid oral dosage form 500 mg Ceftriaxone: powder for injection 2 g Ciprofloxacin: solid oral dosage form 500 mg Clindamycin: injection 600 mg/4 mL, 900 mg/6 mL Phenoxymethylpenicillin: tablet 500 mg Vancomycin: powder for injection 500 mg, 1 g All of the antibiotics for which additional strength formulations are proposed are currently included on the EML is various other formulations and strengths for the indications described below (1).

Summary of evidence

Amoxicillin: solid oral dosage form 1 g Most adult and adolescent patients with mild community-acquired pneumonia or acute bacterial sinusitis can be successfully treated with amoxicillin 1 g every 8 hours for 5 days. The proposed 1 g oral formulation will allow for a reduced pill burden to complete the course of treatment compared with the currently listed 500 mg strength formulation, and should facilitate adherence to treatment. Cefalexin: solid oral dosage form 500 mg Most adult patients diagnosed with exacerbations of chronic obstructive pulmonary disease, can be successfully treated with cefalexin 500 mg every 12 hours for 5 days. For bacterial pharyngitis and mild skin and soft tissue infections, most adult and adolescent patients can be successfully treated with cefalexin 500 mg every 8 hours for 5 days. The proposed 500 mg oral formulation will allow for a reduced pill burden to complete a course of treatment compared with the currently listed 250 mg strength formulation, and should facilitate adherence to treatment. Ceftriaxone: powder for injection 2 g This higher strength formulation is preferable for the treatment of certain infections because it maximizes the chances of bacterial eradication in order to achieve clinical success. For example, in the case of acute bacterial meningitis, a ceftriaxone dose of 2 g every 12 hours is needed to achieve adequate concentrations of the drug in the central nervous system. The recommended duration of treatment is 10 days. For adult patients with hospital-acquired pneumonia and no risk factors for multidrug-resistant infections, ceftriaxone 2 g a day for 7 days is a recommended treatment regimen. For complicated intra-abdominal infections, ceftriaxone 2 g per day for 5 days (in combination with metronidazole) is a recommended treatment in cases where extended-spectrum beta-lactamase strains are not suspected. For severe cases of enteric fever, if ceftriaxone is used, a dose of 2 g per day for 10 days is recommended. Ciprofloxacin: solid oral dosage form 500 mg The proposed higher strength formulation will benefit adult and adolescent patients prescribed ciprofloxacin for infections including acute invasive bacterial diarrhoea, cholera, complicated intra-abdominal infections, enteric fever, low-risk febrile neutropenia and upper urinary tract infections. Treatment regimens recommend ciprofloxacin doses of 500 mg every 12 hours for 3, 5 or 7 days, depending on the indication or, in the case of cholera, a single dose of 1 g. The proposed 500 mg oral formulation will allow for a reduced pill burden to complete the course of treatment compared with the currently listed 250 mg strength formulation, and should facilitate adherence to treatment. Clindamycin: injection 600 mg/4 mL, 900 mg/6 mL The higher strength formulations of clindamycin are preferable for the treatment of bone and joint infections to maximize the chance of bacterial eradication in order to achieve clinical success. For adults and adolescents diagnosed with osteomyelitis, clindamycin is an acceptable treatment option when methicillin-resistant Staphylococcus aureus (MRSA) is suspected or confirmed when antimicrobial susceptibility of MRSA to clindamycin is proven or likely. Intravenous clindamycin at a dose of 600 mg every 8 hours for 4–6 weeks is a recommended dosage regimen in most cases. Clindamycin may also be used in patients allergic to penicillin. Phenoxymethylpenicillin: solid oral dosage form 500 mg Most adult and adolescent patients with mild community-acquired pneumonia, bacterial pharyngitis or dental infections can be successfully treated with phenoxymethylpenicillin 500 mg every 6 hours for 5 days; however, a longer treatment duration may be recommended in some circumstances. The proposed 500 mg strength oral formulation will allow for a reduced pill burden to complete the course of treatment compared with the currently listed 250 mg strength formulation and should facilitate adherence to treatment. Vancomycin: powder for injection 500 mg, 1 g For adult and adolescent patients with high-risk febrile neutropenia when MRSA infection is suspected, weight-based dosing of vancomycin is recommended (15–20 mg/kg every 12 hours). The 500 mg and 1 g strength formulations will allow for the achievement of recommended dose using fewer vials, compared with the currently listed 250 mg strength.

Committee considerations

All proposed formulations are approved by several regulatory agencies including the US Food and Drug Administration and European Medicines Agency, and are available in most countries.

EML recommendations: Inflammatory or other diseases of prostate

First choice	Second choice
MILD TO MODERATE	

ciprofloxacin

cefotaxime

ceftriaxone

SEVERE

cefotaxime

ceftriaxone

1. WHO Model List of Essential Medicines. 21st List. Geneva, World Health Organization; 2019. (https://apps.who.int/iris/handle/10665/330668, accessed 13 August 2021).

