

## Target Product Profile – Gonorrhea – Therapeutic Product

Variable	Minimal Requirement	Ideal Requirement
Product Indication	Uncomplicated urogenital <i>N. gonorrhoeae</i> infections	Uncomplicated urogenital, anorectal and oropharyngeal <i>N. gonorrhoeae</i>
Organisms Covered	<i>N. gonorrhoeae</i> including ceftriaxone-, cefixime- and azithromycin-resistant strains. Intracellular activity. Low frequency of resistance and no cross-resistance to other antibiotics	<i>N. gonorrhoeae</i> including ceftriaxone-, cefixime and azithromycin-resistant strains. Intracellular activity. Low frequency of resistance and no cross-resistance to other antibiotics
Patient Population	Adult and adolescent	Adult, adolescent and pediatric
Treatment Duration	Up to 3 days (oral)	1 day for urogenital <i>N. gonorrhoeae</i> and up to 3 days for anorectal and oropharyngeal <i>N. gonorrhoeae</i> (oral). 1 day for urogenital, anorectal and oropharyngeal <i>N. gonorrhoeae</i> (IM)
Delivery Mode	Oral	Oral or IM
Dosage Form	Tablets/capsules or prefilled vials	Tablets/capsules or pre-filled vials
Regimen	Up to 3 doses (oral) – packaged for partner therapy	1 dose for urogenital gonorrhea and up to 3 doses for anorectal and oropharyngeal gonorrhea (oral). 1 dose for urogenital, anorectal and oropharyngeal gonorrhea(IM) – packaged for partner therapy
Efficacy	Non-inferior to SOC (i.e. ceftriaxone and azithromycin)	Non-inferior to SOC (i.e. ceftriaxone and azithromycin)
Risk/Side Effects	Minimal DDIs with HIV or other STI therapeutics; minimal monitoring required post-treatment; 3-5X therapeutic index	Minimal DDIs with HIV or other STI therapeutics; no monitoring required post-treatment; >5X therapeutic index
Stability	Heat stable, 3-year shelf life	Heat stable, 3-year shelf life
Cost	Equivalent to current treatment regimens	Equivalent to current treatment regimens
Specific Population Claims	Contraindicated in pregnancy/lactation	Safe in pregnancy/lactation and children
Overall Value Proposition: Simple, safe, effective and affordable therapy against hard-to-treat gonorrhea in HIC and LMICs		