Imipenem + cilastatin + relebactam

REJECTED

The Expert Committee, after evaluation, declines to list the medicine proposed in the application.
The Model List of Essential Medicines reports reasons that Committee Members have identified for denying listing.

Section: 6. Anti-infective medicines > 6.2. Antibacterials > 6.2.3. Reserve group antibiotics

EMLc | ATC codes: J01DH56

Indication	Other specified other antibiotic resistant Enterobacterales ICD11 code: MG50.CY
INN	Imipenem + cilastatin + relebactam
Medicine type	Chemical agent
Antibiotic groups	R RESERVE
List type	Complementary
Formulations	**Parenteral > General injections > IV:** 500 mg + 500 mg + 250 mg powder for injection
EML status history	Application rejected in 2023 (TRS 1049)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Main patent is active in several jurisdictions. For more information on specific patents and license status for developing countries visit www.MedsPal.org Read more about patents.
Wikipedia	Imipenem + cilastatin + relebactam
DrugBank	Imipenem, Cilastatin, Relebactam

Summary of evidence and Expert Committee recommendations

The Committee did not recommend inclusion of imipenem + cilastatin + relebactam (IMR) as a Reserve group antibiotic on the complementary list of the EML and EMLc for the treatment of infections caused by multidrug-resistant organisms. The Committee noted that IMR lacks in vitro activity against the carbapenemase genotypes most commonly associated globally with carbapenem resistance in Enterobacterales and that other antibiotics with similar spectrum of activity (e.g. cefiderocol, ceftazidime + avibactam, meropenem + vaborbactam) are already included as Reserve antibiotics on the Model Lists.