Delamanid

Essential medicine status ✓

Section: 6. Anti-infective medicines > 6.2. Antibacterials > 6.2.5. Antituberculosis medicines

EMLc | ATC codes: J04AK06

Indication	Multi-drug resistant Mycobacterium tuberculosis ICD11 code: ML32.00
INN	Delamanid
Medicine type	Chemical agent
List type	Complementary
Additional notes	Medicines for the treatment of multidrug-resistant tuberculosis (MDR-TB) should be used in specialized centres adhering to WHO standards for TB contol.
Formulations	Oral > Solid: 50 mg tablet ; 25 mg tablet (dispersible) (EMLc)
EML status history	First added in 2015 (TRS 994) Changed in 2017 (TRS 1006) Changed in 2019 (TRS 1021) Changed in 2021
Sex	All
Age	Also recommended for children
Age restriction	50 mg tablet: ≥6 years / 25 mg dispersible tablet: ≥3 years
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	Delamanid

Expert Committee recommendation

The Expert Committee recognized the importance of the availability of age-appropriate, child-friendly formulations of medicines for the treatment of multidrug-resistant tuberculosis to meet the dosing and administration needs of children. The Expert Committee noted delamanid, as an oral 50 mg tablet formulation, has been included in the complementary list of the EML since 2015 and EMLc since 2017 for children aged 6 years and older. The Committee noted the acceptable pharmacokinetic data indicating therapeutic delamanid exposure at the recommended dose in children using the proposed 25 mg dispersible tablet formulation, and that there were no additional safety signals beyond those already known in adults. The Expert Committee therefore recommended the addition of the new formulation of delamanid (delamanid 25 mg dispersible tablets) to the complementary list of the EMLc for the treatment of multidrug-resistant tuberculosis in children aged 3 years and older, in line with the updated WHO treatment guidelines. The Committee noted that the availability of the proposed formulation was currently limited, but welcomed the intention of the manufacturer to make this formulation available through the Global Drug Facility.