Bedaquiline

Indication: Multi-drug resistant Mycobacterium tuberculosis

**INN**: Bedaquiline

**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 control.

**Formulations**: Oral > Solid: 100 mg tablet; 20 mg tablet (EMLc)

**EML status history**
- First added in 2015 (TRS 994)
- Changed in 2019 (TRS 1021)
- Changed in 2021 (TRS 1035)

**Sex**: All

**Age**: Also recommended for children

**Age restriction**: ≥ 5 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](http://www.MedsPal.org)

**Wikipedia**: Bedaquiline

**DrugBank**: Bedaquiline

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**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 bedaquiline, as an oral 100 mg tablet formulation, was included on the complementary list of the EML as a reserve second-line medicine for treatment of multidrug-resistant tuberculosis in adults in 2015. In 2019, it was added to the complementary list of the EMLc as a reserve second-line medicine for the treatment of multidrug-resistant tuberculosis in children aged 6 years and older. The Committee noted the acceptable pharmacokinetic data indicating therapeutic bedaquiline exposure at the recommended dose in children using the proposed 20 mg tablets formulation. The Committee therefore recommended the addition of the new formulation of bedaquiline 20 mg tablets to the complementary list of the EMLc for the treatment of multidrug-resistant tuberculosis in children aged 5 years and older, in line with the updated WHO treatment guidelines. The Committee did not recommend the addition of this formulation to the EML for the treatment of adults, noting the high pill-burden required to achieve the recommended adult dose. The Committee also noted that the bioavailability of the 100 mg tablet formulation, when crushed or suspended in water, was not altered. The Committee considered that the 100 mg tablet formulation, crushed or suspended in water, was a suitable alternative for adult patients unable to swallow intact tablets and allowed achievement of the recommended dose with a much lower pill burden.