### Dolutegravir

**Indication**
- Human immunodeficiency virus disease without mention of associated disease or condition, clinical stage unspecified
- ICD11 code: **1C62.Z**

**INN**
- Dolutegravir

**Medicine type**
- Chemical agent

**List type**
- Core

**Formulations**
- Oral > Solid: 50 mg tablet ; 10 mg tablet (dispersible, scored) (EMLc)

**EML status history**
- First added in 2017 (TRS 1006)
- Changed in 2019 (TRS 1021)
- Changed in 2021 (TRS 1035)

**Sex**
- All

**Age**
- Also recommended for children

**Age restriction**
- 10 mg dispersible tablet: ≥ 4 weeks

**Weight restriction**
- 50 mg tablet: ≥ 25 kg / 10 mg dispersible tablet: ≥ 3 kg

**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)
- Read more about patents.

**Wikipedia**
- Dolutegravir

**DrugBank**
- Dolutegravir

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**Expert Committee recommendation**

The Expert Committee recognized that age-appropriate, child-friendly formulations of antiretroviral medicines, when available and quality-assured, are essential to meet the needs of paediatric patients with HIV. The Committee noted evidence that dolutegravir-based regimens show superiority over NNRTI plus protease inhibitor regimens in paediatric patients and that the dolutegravir-based regimens have been recommended in WHO guidelines as the preferred first-line therapy in infants and children aged 4 weeks and older, for which dosing recommendations and age-appropriate formulations are available. The Committee therefore recommended the inclusion of the new formulation of dolutegravir 10 mg dispersible tablets to the core list of the EMLc for the treatment of children 4 weeks of age and older and weighing at least 3 kg. The Committee noted however that the 10 mg dispersible tablet formulation and the 50 mg film-coated tablet formulation of dolutegravir have not been shown to be bioequivalent and should not be used interchangeably in patients on a milligram-to-milligram basis.