

F.4 Bedaquiline (20 mg tablet)

MSF strongly supports the application for the inclusion of bedaquiline 20 mg tablet in both the WHO Model List of Essential Medicines (EML) and the WHO Model List of Essential Medicines for Children (EMLc), in the complementary list of anti-tuberculosis medicines, as a second-line drug for the treatment of multidrug-resistant tuberculosis (MDR-TB).

According to the 2019 WHO Global Tuberculosis Report, most multidrug-resistant or rifampicin-resistant tuberculosis patients can be treated with fully oral anti-tuberculosis medicines regimens: a short course treatment with a combination of fluoroquinolone, bedaquiline and linezolid. These fully oral regimens allow to avoid injectable anti-tuberculosis medicines regimens, as aminoglycosides and capreomycin, presenting risks of nephrotoxicity and ototoxicity.

According to the 2020 WHO Consolidated Guidelines on Tuberculosis, Module 4: Treatment - Drug-Resistant Tuberculosis Treatment, bedaquiline is recommended for all-oral, short or longer regimens for MDR-TB in adults and children older than 6 years.

In 2015, MSF has supported the inclusion of bedaquiline 100 mg tablet in the EML, in the complementary list of anti-tuberculosis medicines, for use in adults and in 2019, the inclusion of bedaquiline 100 mg tablet in the EMLc, for use in children older than 6 years.

In 2019, MSF has emphasized in its support that access to child-friendly formulations like scored tablets and dispersible tablets easily dissolved in water should reach internationally agreed quality standards and should be promoted. For young patient unable to swallow, this scored tablet will be dissolved meticulously in water, then mixed with other beverage or soft food, if necessary. MSF warmly welcomes this paediatric scored tablet formulation, essential to increase ease and safety of administration as well as adherence to treatment.

MSF would like to draw the attention of the Expert Committee to the following facts:

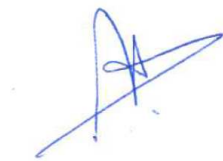
- This inclusion will serve as a basis for National Essential Medicines lists and therefore will facilitate importations, alert manufacturers about the need for local registrations and will increase interest for pediatrics formulations. This inclusion will help to use this medicine more widely, in order to improve outcomes and reduce mortality for the patients developing MDR-TB.

- MSF also supports the request to extend the current age recommendation (children ≥ 6 years) to children ≥ 5 years old and weighing at least 15kg for the bedaquiline 100 mg oral tablet in the EMLc.
- The US FDA and EMA approvals for the use of bedaquiline in pediatric patients 5 years to less than 18 years of age and weighing at least 15 kg were granted in May 2020 and January 2021, respectively.
- Previously all products in the WHO Model List of Essential Medicines for Children were also on the WHO Model List of Essential Medicines: if this logic is maintained, the 20 mg scored tablet formulation of bedaquiline should also be included on the WHO Model List of Essential Medicines.

MSF has been using bedaquiline 100 mg tablet in its programs since December 2012 and bedaquiline 20 mg scored tablet since 2020.

In light of these elements, MSF urges the 23rd Expert Committee on the Selection and Use of Essential Medicines to include bedaquiline 20 mg scored tablet in the WHO Model List of Essential Medicines for Children, in the complementary list of anti-tuberculosis medicines in children and to extend the current age recommendation (children ≥ 6 years) to children ≥ 5 years old and weighing at least 15kg.

For Médecins Sans Frontières



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