




EMLc

ATC codes: [P01CA02](#)

Indication	Chagas disease ICD11 code: 1F53.Z
INN	Benznidazole
Medicine type	Chemical agent
List type	Core
Formulations	Oral > Solid: 100 mg tablet ; 50 mg tablet (scored) ; 12.5 mg tablet (EMLc)
EML status history	First added in 1987 (TRS 770) Changed in 2003 (TRS 920) Changed in 2007 (TRS 950) Changed in 2013 (TRS 985)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Patents have expired in most jurisdictions Read more about patents. 
Wikipedia	Benznidazole 
DrugBank	Benznidazole 

Summary of evidence and Expert Committee recommendations

Benznidazole 12.5 mg and 50 mg scored solid oral dosage forms were added to the core list for the treatment of infections of *Trypanosoma cruzi*. An application for adding the 12.5-mg benznidazole tablet presentation was received from the Drugs for Neglected Diseases initiative (DNDi), Rio de Janeiro, Brazil. Another application to add the 50-mg scored tablet was received from the Department for Control of Neglected Tropical Diseases, WHO, based on the same considerations as those for the 12.5-mg tablet. A recent WHO report estimated that 10 million people worldwide are infected by *Trypanosoma cruzi*, mostly in the endemic areas of 21 Latin American countries, but also in non-endemic countries as a consequence of population mobility (1). Most infections occur during childhood, and there are also congenital infections. However, until recently the only registered dosage form of benznidazole, the first-line treatment for Chagas disease, was a 100-mg tablet suitable for adults. Despite the heterogeneity of studies presented in terms of objectives, geographical location, age ranges, numbers of children included, therapeutic schemes used, duration of post-treatment monitoring and the cure control tests deployed, there is clear evidence of the efficacy of benznidazole for the treatment of children infected by *Trypanosoma cruzi*, including those less than a year old, and this evidence suggests that greater efficacy is associated with early treatment. Seroconversion rates vary from 87% at 36 months (3) (100% in the 0–3 months age group) to 100% (3) at 24 months in children up to 2 years of age. Adverse events during treatment are more frequent and more severe in adults than in children, and are particularly infrequent in children below 1 year. Fewer neurological events were noted among children, who present mainly with dermatological and gastrointestinal adverse events. Treatment with benznidazole is of long duration and usually is given outside the hospital setting. Benznidazole is listed in the EMLc and WHO recommends it for the treatment of neonates, infants and children. The recommended dose is 5–10 mg/kg per day. The Expert Committee noted that the proposed formulations of benznidazole that are essential for the treatment of *T. cruzi* infections achieve paediatric doses more easily even in ambulatory care settings. The 12.5-mg tablet is registered in Brazil and the 50-mg tablet is

registered in Argentina. Taking into consideration the need for child-friendly formulations of benznidazole, the Expert Committee decided to add both the 12.5-mg and 50-mg scored tablets to the EMLc. 1. Working to overcome the global impact of neglected tropical diseases: first WHO report on neglected tropical diseases. Geneva: World Health Organization; 2010. 2. Schijman AG, Altcheh J, Burgos JM, Biancardi M, Bisio M, Levin MJ, et al. Aetiological treatment of congenital Chagas' disease diagnosed and monitored by the polymerase chain reaction. *J Antimicrob Chemother.* 2003;52(3):441-9. <http://dx.doi.org/10.1093/jac/dkg338> PMID:12917253 3. Russomando G, de Tomassone MM, de Guillen I, Acosta N, Vera N, Almiron M, et al. Treatment of congenital Chagas' disease diagnosed and followed up by the polymerase chain reaction. *Am J Trop Med Hyg.* 1998;59(3):487-91. PMID:9749649

