# Amphotericin b

Essential medicine status

Section: 6. Anti-infective medicines > 6.5. Antiprotozoal medicines > 6.5.2. Antileishmaniasis medicines

EMLc | ATC codes: J02AA01

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| **Indication** | Visceral leishmaniasis ICD11 code: 1F54.0 |
| **INN** | Amphotericin B |
| **Medicine type** | Chemical agent |
| **List type** | Core |
| **Formulations** | Parenteral > General injections > IV: 50 mg powder for injection in vial (as deoxycholate or liposomal complex) |
| **EML status history** | First added in 1995 (TRS 867)<br>Changed in 2007 (TRS 950)<br>Changed in 2009 (TRS 958) |
| **Sex** | All |
| **Age** | Also recommended for children |
| **Therapeutic alternatives** | The recommendation is for this specific medicine |
| **Patent information** | Patents have expired in most jurisdictions<br>Read more about patents. |
| **Wikipedia** | Amphotericin b |
| **DrugBank** | Amphotericin b |

## Summary of evidence and Expert Committee recommendations

Amphotericin B was moved to the core list of the EML and EMLc for the treatment of visceral leishmaniasis. The EMLc Subcommittee noted that the incidence of this infection is increasing in different parts of the world and that children account for a significant proportion of those with visceral leishmaniasis in disease-endemic areas. Morbidity and mortality related to this infection are substantial. Resistance to conventional therapy has been recorded, but there is inadequate information regarding the magnitude of this problem. The available data, although not of good quality, suggest that liposomal amphotericin B is effective for the treatment of visceral leishmaniasis and is safe in children (1,2). However, the Subcommittee is concerned that there are insufficient data to show how liposomal amphotericin B compares with the original formulation of this drug in terms of efficacy and safety in the treatment of visceral leishmaniasis. The Subcommittee noted that the different dosages and schedules tested have shown a good response and hence there could be flexibility in the dosage schedule. Several regimens have used a total dose of approximately 20 mg/kg and WHO recommends this dosage (3). The duration of in-patient therapy can vary, but is shorter than that with conventional therapies. Safety data suggest that liposomal amphotericin B may be better than other therapies, but there is a paucity of good quality data on which to base conclusions. The cost of therapy with liposomal amphotericin B can be significantly higher than that of conventional therapies. The Subcommittee was made aware of the preferential pricing offer which could help in addressing the issues of cost and availability associated with the procurement of liposomal amphotericin B in developing countries. The Subcommittee has noted that liposomal amphotericin B is being used as first-line therapy in some high-income countries. In other countries it is considered as second-line therapy, mainly due to cost. The Subcommittee decided that liposomal amphotericin B should be added to the Core List of the EMLc for the treatment of visceral leishmaniasis. When the cost of the liposomal formulation is similar to that of the original formulation of amphotericin B, the liposomal formulation may be preferable in the light of data on other fungal infections that support a lower incidence of nephrotoxicity. It also recommended that good quality clinical data on the safety and efficacy of liposomal amphotericin B in children with visceral leishmaniasis be collected

prospectively. The Expert Committee reviewed Section 6.5.2, medicines for leishmaniasis, for conconrdance between the EML and EMLc, and on the advice of the WHO Department of Control of Neglected Tropical Diseases, made the same changes to the complete EML. References: 1. di Martino L et al. Treatment of visceral leishmaniasis in children with liposomal amphotericin B. Journal of Pediatrics, 1997, 131:271–7. 2. Syriopoulou V et al. Two doses of a lipid formulation of amphotericin B for the treatment of Mediterranean visceral leishmaniasis. Clinical Infectious Diseases, 2003, 36:560–6. 3. Bern C et al. Liposomal amphotericin B for the treatment of visceral leishmaniasis. Clinical Infectious Diseases, 2006, 43:917–24.