References for Application for inclusion of paromomycin in the WHO Model List of Essential Medicines

6 (a) Visceral leishmaniasis – disease burden.


6 (b) Inadequacy of existing medicines for VL

Resistance to sodium stibogluconate

Sundar S. Drug resistance in Indian visceral leishmaniasis. Tropical Medicine and International Health 2001, 6 (11) 849-54


References for Application for inclusion of paromomycin in the WHO Model List of Essential Medicines

**Pentavalent antimonials - Reviews of antimonial use**


**Pancreatic, Cardiac and Other Antimonial Toxicity**


Gasser RA Jr; Magill AJ; Oster CN; Franke ED; Grogl M; Berman JD. Pancreatitis induced by pentavalent antimonial agents during treatment of leishmaniasis. Clin Infect Dis. 1994 Jan; 18(1): 83-90


Hepburn NC; Nolan J; Fenn L; Herd RM; Neilson JM; Sutherland GR; Fox KA. Cardiac effects of sodium stibogluconate: myocardial, electrophysiological and biochemical studies. QJM. 1994;87:465-7
References for Application for inclusion of paromomycin in the WHO Model List of Essential Medicines

Mechanisms of antimonial toxicity

Franco MA; Barbosa AC; Rath S; Dorea JG. Antimony oxidation states in antileishmanial drugs. Am J Trop Med Hyg. 1995 May; 52(5): 435-7

Dep, P.D.; Viana, M.C.; Falqueto, A.; Dietze, R. Comparative study between sodium stibogluconate BP88 (Shandong Xinhua - China) and meglumine antimoniate (Rhodia - Brazil) on the treatment of cutaneous leishmaniasis, in the endemic area Corte de Pedra, Bahia, Brazil. Revista da Sociedade Brasileira de Medicina Tropical 2000;33:535-43.


Foetal loss in pregnant women treated with antimonials


Increased mortality associated with antimonials


Amphotericin B use and toxicity


References for Application for inclusion of paromomycin in the WHO Model List of Essential Medicines

**Pentamidine use and toxicity**


**Liposomal amphotericin B.**


**Miltefosine**


7. Treatment details - SUMMARY OF PRODUCT CHARACTERISTICS
(This section comprises the package insert for Paromomycin IM Injection)

8 /9. Comparative effectiveness and safety

Phase 2 studies of paromomycin


References for Application for inclusion of paromomycin in the WHO Model List of Essential Medicines

**Phase 3 study:**

- Interim data presented at the ASTMH meeting Nov 2004 (see attached abstract)
- Submitted manuscript (see attached)
- Pharmacokinetic data presented at ICAAC 2006 (see attached abstract)