Triclabendazole, Tablet 250 mg

WHO Model Formulary information

Triclabendazole, a benzimidazole compound is highly effective and well tolerated, as a single dose or two divided doses, for both Fasciola and Paragonimus infections.

Uses: fascioliasis; paragonimiasis.

WHO Essential Medicines Library. Rationale for inclusion

Date added: 1977.
For the treatment of fascioliasis and paragonimiasis.
Well tolerated and effective.
Technical report.
WHO: Safety review of niclosamide, pyrantel, triclabendazole and oxamniquine.

Evidence

No meta-analyses or systematic reviews have been carried out on this issue.

The Secretariat identified a number of clinical trials demonstrating benefits of triclabendazole treatment. The most recent of those are presented:

   a. In 165 patients randomly allocated to receive 10 mg/kg, p.o., triclabendazole for 1, 2 or 3 days (single-, double- and triple-dose groups, respectively) a sharp decrease in the proportion of clinical signs and symptoms was observed in all groups immediately after treatment. All cases were cured on day 60. No cases of toxic hepatitis were observed.

   a. An open clinical trial compared the efficacy of 2 single-day regimens of triclabendazole (either a single dose or 2 doses of 10 mg/kg), involving a total of 154 Ecuadorian patients (from 1991 to 1993). Both regimens were associated with a rapid parasitological response (clearance of Paragonimus eggs from sputum), resolution of most clinical symptoms and radiological signs. At 3 months after treatment, the cure rate (clearance of eggs from sputum) was 90.9% in the 2-dose group and 84.4% in the single-dose group. Re-treatment with a second 2-dose regimen cured all patients by 1 year of follow-up. Only mild adverse effects were observed.

   a. A total of 134 asymptomatic cases of established Fasciola infection were treated: 68 individuals received a single dose of 10 mg/kg and 66 individuals received 2 doses of 10 mg/kg on 2 consecutive days. Cure was assessed 5 weeks after treatment and 79.4% of the first group and 93.9% of the second group were cured. The drug was well tolerated; no serious side-effects were noted.

Secretariat’s conclusion

The identified recent trials of triclabendazole for fascioliasis and paragonimiasis are open label, not all of them are randomized, there is no control with alternative comparators: Navo-Ocampo 2004¹, Calvopiña 2003², el-Morshedy 1999³. Nonetheless the results of these trials suggest that triclabendazole in the treatment of fascioliasis and paragonimiasis is effective and well tolerated. In view of the major public health importance of fascioliasis and paragonimiasis the Committee is requested to consider retaining triclabendazole on the Model List.

