

May 19 2021

To: Expert Committee on Selection and Use of Essential Medicines

Subject: Comment on the Application: I.1 Albendazole, Mebendazole, Praziquantel – taeniid cestode cysts – EML and EMLc

Dear Expert Committee on Selection and Use of Essential Medicines,

We have reviewed the application for inclusion of albendazole, mebendazole and praziquantel on the WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc) for the indication of treatment of taeniid cestode cysts. The application proposes using mebendazole to treat Alveolar or Cystic Echinococcosis if the drug of choice, albendazole, is not available or is purely tolerated.

Herein we comment on Section 5. Dose forms and strengths proposed for inclusion; including adult and age-appropriate paediatric dose forms/strengths (if appropriate) of the application:

"MEBENDAZOLE – CE & AE

Presentation: Tablet (chewable) 500mg

The dose required for treatment of echinococcosis (40-50mg/kg) is high compared to that required for treatment of other parasitic infections (100 or 200 mg), hence the 500 mg tablets are preferred for echinococcosis treatment. The 100mg tablets are likely to be preferred for intestinal parasites that require lower doses.

Availability: The presentation of tablets 500mg is the same presentation used for preventive chemotherapy for soil-transmitted helminths. WHO receives a donation of 500mg tablets from Johnson & Johnson (Vermox). It is not widely available on the market."

Janssen would like to point out that other 500 mg formulations of mebendazole, including generics, are broadly available on the market and therefore the availability statement should be updated accordingly to keep access to the treatment broader and sustainable.

Thank you for your consideration.

Respectfully,



Sergio Fonseca, MD
Sr. Director Compound Development Team Leader
Established Products, Global Medical Organization

Janssen R&D, LLC.
1125 Trenton-Harbourton Rd.
Titusville, NJ 08560, US