19th Expert Committee on The Selection and Use of Essential Medicines  
April 8-12 2013  

Expert peer review on application for FOMEPIZOLE

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      Fomepizole is a competitive inhibitor of alcohol dehydrogenase. In comparison with ethanol in treatment of methanol intoxication, fomepizole has not the inhibitor effect on CNR and hypoglycemia.

      Administration by IV 15mg/kg then 10mg/kg every 12 hours X 4 sessions. Then, 15mg/kg by IV every 12 hours until the blood methanol concentration <20mg/dL.

   c. Please provide any additional relevant information with reference

      Fomepizole is also used for treatment of pediatric ethylene and diethylene glycol, butoxyethanol and methanol poisoning


2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes

   Adverse effects: The most frequent adverse effects associated with fomepizole are headache, nausea, dizziness, drowsiness and taste disturbance. Abdominal pain, vomiting, diarrhea, hypotension, tachycardia, hypersensitivity reactions and raised hepatic enzymes have also been reported

   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   c. Please provide any additional relevant information with reference
3. Assessment of cost and availability
   a. Have all relevant data on cost provided
      Yes    No (if no, please provide reference and information)

      Fomepizole is available as proprietary medicines. There are no generic products. High price of
      Fomepizole due to no generic competition.

   b. Summarize the data on cost and cost effectiveness, in comparison to what is listed in EML where
      applicable (limit to 2 to 3 sentences)

      The treatment cost with fomepizole is higher than treatment with ethanol or/and other methanol
      antidote.

   c. Please provide any additional relevant information with reference

   d. Is the product available in several low and middle income countries?

      Fomepizole is proprietary preparations. There are no generic products in low and middle income
      countries

4. Assessment of public health need
   a. Please provide the public health need for this product (1-2 sentences)

   b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2
      international preferable

      Fomepizole is not listed in 5\textsuperscript{th} Vietnam EML (2005), 8\textsuperscript{th} Draft of 6\textsuperscript{th} Vietnam EML, EML of India

5. Are there special requirements for use or training needed for safe/effective use?
   No

6. Is the proposed product registered by a stringent regulatory authority?
   Yes

7. Any other comments

8. What is your recommendation to the committee (please provide the rationale)

      Fomepizole could be listed in Complementary List due to its efficacy and safety in treatment of
      methanol, ethylene and diethylene glycol poisoning, especially in pediatric patients but the cost of
      treatment is higher.