

19th Expert Committee on The Selection and Use of Essential Medicines

April 8-12 2013

Expert peer review on application to add ofloxacin under ophthalmological preparations

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      No (if no, please provide reference and information)

      Other clinical trials are also available. Ofloxacin is shown to be more efficacious than gentamicin in ocular infections.

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

      Fluoroquinolones as a class are useful antimicrobial agents and have been shown to be superior to gentamicin when used topically for ocular infections. They have a broad spectrum of activity and act on the commonly seen bacterial pathogens in the eye which cause keratitis and conjunctivitis. There is only one topical agent listed in the EML for ocular bacterial infections which is gentamicin.

   c. Please provide any additional relevant information with reference

2. Assessment of safety

   a. Have all relevant studies on safety been included
      Yes (if no, please provide reference and information)

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

      Ofloxacin is well tolerated by patients and adverse effects are minimal. However, there has been a reported case of Stevens-Johnson syndrome, which progressed to toxic epidermal necrolysis, in a patient who received topical ophthalmic ofloxacin. Mild stinging when applied and some redness is seen in a few patients.

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability

   a. Have all relevant data on cost been provided
      Yes
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)

Ofloxacin is not an expensive drug as generic versions are available. In India a 3 ml bottle costs approximately 2 USD.

c. Please provide any additional relevant information with reference.

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

Yes

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

Trauma to the eye and subsequent infection is one of the common causes of blindness in developing countries. Hence antimicrobial agents such as ofloxacin with a broad spectrum of activity need to be included in the EML.

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

Yes.


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. It has been approved by US FDA and in UK and Australia

7. Any other comments

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

Ofloxacin should be added to the EML as it has proven to be efficacious, safe and is cost effective. It should be included in the EML with a square box symbol which is indicative of the drug being an example of the class – in this case fluoroquinolones.