NATAMYCIN D01AA02

(1) Does the application adequately address the issue of the public health need for the medicine?

Yes

In warm, humid climates, approximately 50% of cases of microbial keratitis are caused by fungi. The major burden of fungal keratitis falls on rural populations in low and middle income countries.

(2) Have all important studies that you are aware of been included in the application?

Yes

(3) Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed use?

Yes

It is effective against filamentous fungi, particularly for infections caused by Fusarium. However, because of poor ocular penetration, it has primarily been useful in cases with superficial corneal infection. It is not effective against Candida.


Natamycin is commercially available, and there is more experience with using it. Topical voriconazole has a wider antifungal coverage. Voriconazole may be the first choice in patients who have a higher risk for Candida keratitis but also require a good antifungal coverage against other species.

(4) Is there evidence of efficacy in diverse settings and/or populations?

No

(5) Has the application adequately considered the safety and adverse effects of the medicine? Are there any adverse effects of concern, or that may require special monitoring?
Yes

Topical natamycin is generally well tolerated. There are no known ethnicity or gender specific toxicities.

ADDITIONAL CONSIDERATIONS

(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?

Yes

Eye examination every 2 days until the ulcer starts improving. The frequency of treatment is adjusted according to the clinical response.

(7) Are there any issues regarding the registration of the medicine by regulatory authorities? (e.g., recent registration, new indications, off-label use)

No

Approved by the FDA since the 60s

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?

Yes

In a SEARO 2004 guidelines for the Management of Corneal Ulcer

(9) Please comment briefly on issues regarding cost and affordability of this medicine.

The generic Natamycin Ophthalmic is manufactured by 7 companies. It may not be available in some countries.

(10) Any additional comments?

None

(11) Please summarise the action you propose the Expert Committee takes.
I propose the inclusion NATAMYCIN OPHTHALMIC SUSPENSION, 5% in the 20\textsuperscript{th} WHO Model List of Essential Medicines as well as in the children list. It is to be included in section: 6.3 Antifungal medicines.