

# FORMULATION OF VORICONAZOLE OVULES AND EFFICACY IN VULVOVAGINAL CANDIDIASIS BY CANDIDA GLABRATA: A CASE REPORT

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## BACKGROUND AND IMPORTANCE

*Candida glabrata* is a vaginal colonizer causing **Vulvovaginal Candidiasis (VVC)**, usually asymptomatic. Typical first-line therapies, boric acid or nystatin ovules, are not effective due to their inherent resistance. Flucytosine, amphotericin B or voriconazole would be the treatment of choice.

## AIM AND OBJECTIVES

To formulate **voriconazole ovules (VO)** and describe our clinical experience in the treatment of **VVC** by *C.glabrata*.

## MATERIAL AND METHODS



The patient

A woman of 52-year-old

Symptoms: vulvar pain, irritation and burning

She was treated with:

Oral fluconazole

Oral voriconazole

Topical amphotericin B

Boric acid ovules

Oral fluconazole and amphotericin B

Her symptoms did not resolve and the culture remained positive.

- A bibliographic search was carried out (pharmacopoeia, uptodate and pubmed) about **VO** formulation and its solubility in polyethylene glycol (PEG) was confirmed. Other magistral formulations of **ovules** containing PEG as an excipient were used as a reference for formulation design.

- Galenic validation included:
  - Organoleptic controls
  - Physical tests: mass uniformity and dissolution time

Finally, treatment efficacy was assessed by symptom resolution and negativisation of the vaginal exudate culture.

## RESULTS

Modus operandi for 30 units VO 15 mg with an excess of 20%:



1 Melt: 81,36 g PEG 400 and 54,72 g PEG 4.000

2 Crush 11 tablets of voriconazole 50 mg in a mortar and pestle. Work in biological safety cabinet type I if there is a reproductive risk, otherwise Personal Protective Equipment (PPE).

3 Add powder to the melted mass and homogenize

4 Pour mixture into 3 g ovule moulds and allow to cool

5 Unmould, package and label

Regarding galenic validation, the surface of VO was shiny, smooth and without cracks. All were within the weight range ( $\pm 5$ ) and took 34 minutes to dissolve. The given expiry date was 6 months.

The patient started treatment with daily VO

After three months of treatment

Resolution of symptoms and negative cultures

The frequency of administration increase

To every 48 hours and then to every 72 hours until 6 months of treatment without reactivation of the infection

## CONCLUSIONS AND REVELANCE

The **magistral formulation** was validated and proved to be effective in the treatment of VVC by *C.glabrata*.

3PC-021

