

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**214900Orig1s000**

**MULTI-DISCIPLINE REVIEW**

**Summary Review**

**Office Director**

**Cross Discipline Team Leader Review**

**Clinical Review**

**Non-Clinical Review**

**Statistical Review**

**Clinical Pharmacology Review**

### NDA Multi-Disciplinary Review and Evaluation

<b>Application Type</b>	NDA
<b>Application Number</b>	214900
<b>Priority or Standard</b>	Priority
<b>Submit Date</b>	October 01, 2020
<b>Received Date</b>	October 01, 2020
<b>PDUFA Goal Date</b>	June 01, 2021
<b>Division/Office</b>	Division of Anti-Infectives/Office of Infectious Diseases
<b>Review Completion Date</b>	June 1, 2021
<b>Established/Proper Name</b>	Ibrexafungerp
<b>(Proposed) Trade Name</b>	BREXAFEMME
<b>Pharmacologic Class</b>	Triterpenoid antifungal
<b>Code names</b>	SCY-078, MK-3118
<b>Applicant</b>	SCYNEXIS, Inc.
<b>Dosage form</b>	Tablet
<b>Applicant proposed Dosing Regimen</b>	300 mg (two tablets of 150 mg) twice a day for one day
<b>Applicant Proposed Indication/Population</b>	Treatment (b) (4) adult women with vulvovaginal candidiasis
<b>Applicant Proposed SNOMED CT Indication Disease Term for each Proposed Indication</b>	72605008 Candidal vulvovaginitis (disorder)
<b>Recommendation on Regulatory Action</b>	Approval
<b>Recommended Indication/Population</b>	Treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC)
<b>Recommended SNOMED CT Indication Disease Term for each Indication</b>	72605008 Candidal vulvovaginitis (disorder)
<b>Recommended Dosing Regimen</b>	300 mg (two tablets of 150 mg) administered approximately 12 hours apart for one day; with concomitant use of a strong CYP3A inhibitor, adjust dose to 150 mg (one of the 150 mg tablet) administered approximately 12 hours apart for one day

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