

Scynexis – Recall of Brexafemme® (ibrexafungerp)

- On September 27, 2023, Scynexis announced a consumer-level recall of two lots of Brexafemme (ibrexafungerp) tablets due to potential cross contamination with a non-antibacterial beta-lactam drug substance in the ibrexafungerp citrate used to manufacture the Brexafemme tablets.
- Brexafemme was distributed nationwide beginning December 2022.

Product Description	NDC Number	Lot Number (Exp Date)
Brexafemme (ibrexafungerp) 150 mg blister packs	75788-115-04	LF21000008 (11/2023); LF22000051 (11/2025)

- Brexafemme is indicated in adult and post-menarchal pediatric females for the treatment of vulvovaginal candidiasis and for the reduction in the incidence of recurrent vulvovaginal candidiasis.
- The potential cross contamination with a non-antibacterial beta-lactam drug substance could lead to hypersensitivity reactions such as swelling, rash, urticaria and anaphylaxis, a potentially life-threatening adverse reaction.
- To date, Scynexis has not received any reports of adverse events established to be due to the possible beta-lactam cross contamination.
- Anyone with the affected lot on hand should stop distribution and return product. Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
- Contact Sedgwick at 1-877-551-7154 for questions regarding this recall.