

## Scynexis – Recall of Brexafemme® (ibrexafungerp)

- On September 27, 2023, <u>Scynexis announced</u> a consumer-level recall of two lots of <u>Brexafemme</u>
   (<u>ibrexafungerp</u>) 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<br>(Exp Date)                      |
|---|--------------|---|
| Brexafemme (ibrexafungerp) 150 mg blister packs | 75788-115-04 | LF21000008 (11/2023);<br>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 lifethreatening 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.



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