

Odevixibat Pregnancy and Lactation Surveillance Program: A Study to Evaluate the Safety of Odevixibat During Pregnancy and/or Lactation

NCT06258902

Status RECRUITING
Sponsor Ipsen
Enrollment 20 participants

Key Eligibility Criteria

Inclusion (2)

- Exposure to at least 1 dose of odevixibat at any time during pregnancy (from 1 day prior to conception to pregnancy outcome) and/or at any time during lactation (up to 12 months of infant age or weaning, whichever comes first).
- Informed consent or IRB-/EC-approved waiver of informed consent (not applicable if reported by Albreo PV according to usual pharmacovigilance practices)

Exclusion (1)

- Refusal to provide informed consent, if required

Locations (1 total)

Virtual Research Coordination Center Odevixibat (BYLVAY) Pregnancy Surveillance Program, Wilmington, North Carolina, United States