

Faslodex[®] (fulvestrant) – Expanded indication

- On November 15, 2017, [AstraZeneca announced](#) the FDA approval of [Faslodex \(fulvestrant\)](#) for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with [Ibrance[®] \(palbociclib\)](#) or [Verzenio[®] \(abemaciclib\)](#) in women with disease progression after endocrine therapy.
 - Previously, this indication was only approved for use in combination with Ibrance.
 - Faslodex is also indicated for the treatment of HR-positive, HER2-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy or HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy.
- The expanded indication for Faslodex was based on data from a clinical study (MONARCH 2) of 669 women with HR-positive, HER2-negative advanced breast cancer randomized to Faslodex plus Verzenio vs. Faslodex plus placebo. Primary efficacy measures were progression free survival (PFS) and objective response rate (ORR).
 - The results showed a statistically significant increase in median PFS of 7.1 months (16.4 months vs. 9.3 months) in patients who received Faslodex plus Verzenio vs. Faslodex plus placebo (HR: 0.553; 95% CI: 0.449, 0.681; p < 0.0001).
 - The ORR with Faslodex plus Verzenio was greater (48.1%, 95% CI: 42.6, 53.6) vs. Faslodex plus placebo (21.3%, 95% CI: 15.1, 27.6).
- When Faslodex is used in combination with Ibrance or Verzenio, the recommended dose of Faslodex is 500 mg administered intramuscularly into the buttocks (gluteal area) slowly (1 – 2 minutes per injection) as two 5 mL injections, one in each buttock, on days 1, 15, 29 and once monthly thereafter.
 - When Faslodex is used in combination with Verzenio, the recommended dose of Verzenio is 150 mg orally, twice daily.
 - Refer to the Faslodex drug label for dosing recommendations for all other indications.