

Belviq XR® (Iorcaserin) – New Formulation Approval

- On July 19, 2016, <u>Eisai announced</u> the <u>FDA approval</u> of <u>Belviq XR (lorcaserin)</u> extended-release oral tablets, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m² or greater (obese) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, dyslipidemia, type 2 diabetes).
 - The safety and efficacy of coadministration with other products for weight loss have not been established.
 - The effect of Belviq XR on cardiovascular morbidity and mortality has not been established.
- Lorcaserin is also available as <u>Belviq</u>, an oral 10 mg tablet.
- The approval of Belviq XR was based on clinical data that confirmed bioequivalence of once daily 20 mg tablets with twice daily 10 mg tablets.
- The recommended dose of Belviq XR is one tablet (20 mg) orally once daily. The dose of Belviq is one tablet (10 mg) orally twice daily.
 - Discontinue if 5% weight loss is not achieved by week 12.
- Eisai plans to launch Belviq XR in the fall of 2016. Belviq XR will be available as 20 mg extended-release tablets.



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