

Livmarli[®] (maralixibat) – Expanded indication

- On March 14, 2023, [Mirum Pharmaceuticals](#) announced the [FDA approval](#) of [Livmarli \(maralixibat\)](#), for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 3 months of age and older.
 - Livmarli was previously approved for this indication in patients 1 year of age and older.
- The approval of Livmarli for the expanded indication in patients 3 to < 12 months of age was supported by an open-label study of Livmarli which showed a similar safety, tolerability, and pharmacokinetic profile to patients with ALGS ≥ 12 months of age.
- The recommended dosage of Livmarli is 380 mcg/kg orally once daily, taken 30 minutes before a meal in the morning. The starting dosing is 190 mcg/kg administered orally once daily; after one week, the dose should be increased to 380 mcg/kg once daily, as tolerated. The maximum daily dose volume for patients above 70 kg is 3 mL or 28.5 mg per day.
 - Refer to the dosing by weight guidelines presented in the Livmarli drug label.