

Lialda® (mesalamine) – Expanded indication

- On June 26, 2020, the [FDA approved](#) Takeda's [Lialda \(mesalamine\)](#), for the treatment of mildly to moderately active ulcerative colitis in pediatric patients weighing at least 24 kg.
- Lialda is also approved for the induction and maintenance of remission in adult patients with mildly to moderately active ulcerative colitis.
- Lialda is also available generically.
- The approval of Lialda for the expanded indication was based on a randomized, double-blind study in pediatric patients with mildly to moderately active ulcerative colitis. The study consisted of two treatment phases, an initial 8-week phase and a 26-week phase. The overall population consisted of 105 patients, of whom 27 patients participated in both the 8-week and 26-week phases. Patients received a low or a high weight-based dosage of Lialda. The primary endpoint was defined by the partial Ulcerative Colitis Disease Activity Index (UC-DAI) less than or equal to 1 (with rectal bleeding equal to 0, stool frequency less than or equal to 1, and Physician's Global Assessment equal to 0).
 - In the 8-week phase, of the 26 patients in the recommended Lialda dosage arm, 65% achieved the primary endpoint.
 - In the 26-week phase, of the 42 patients in the recommended Lialda dosage arm, 55% achieved the primary endpoint. The arm with a higher than recommended Lialda dosage was not more effective and is not recommended.
- The most common adverse reactions (≥ 5%) with Lialda use in pediatric patients were abdominal pain, upper respiratory tract infection, vomiting, anemia, headache, and viral infection.
- The recommended oral dosage of Lialda in pediatric patients weighing at least 24 kg who can swallow tablets whole is shown in the table below.
 - Refer to the Lialda drug label for dosing in adult patients.

Weight of pediatric patient	Once daily Lialda dosage	
	Week 0 to week 8	After week 8
24 kg to 35 kg	2.4 g (two 1.2-g tablets)	1.2 g (one 1.2-g tablet)
Greater than 35 kg to 50 kg	3.6 g (three 1.2-g tablets)	2.4 g (two 1.2-g tablets)
Greater than 50 kg	4.8 g (four 1.2-g tablets)	2.4 g (two 1.2-g tablets)