



## Aczone<sup>®</sup> (dapson) – Expanded indication

- On September 10, 2019, the [FDA approved](#) Almirall's [Aczone \(dapson\) gel 7.5%](#), for the topical treatment of acne vulgaris in patients 9 years of age and older.
  - Aczone was previously approved for this indication in patients 12 years of age and older.
- Dapson is also available generically as a [5% gel](#). The 5% gel formulation is approved for topical treatment of acne vulgaris.
- The use of Aczone gel 7.5% in patients 9 to 11 years of age was supported by evidence from adequate and well-controlled clinical trials in 1,066 patients 12 years of age and older and with additional pharmacokinetic and safety data in pediatric patients 9 to 11 years of age from an open label study of 100 patients with acne.
- The recommended dosing for Aczone gel 7.5% is a pea-sized amount applied in a thin layer to the entire face once daily. In addition, a thin layer may be applied to other affected areas once daily.
  - If there is no improvement after 12 weeks, treatment with Aczone should be reassessed.



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