

Uceris® (budesonide) – First-time generic

- On July 9, 2018, <u>Teva launched</u> an <u>AB-rated</u> generic version of Salix Pharmaceuticals' <u>Uceris</u> (<u>budesonide</u>) extended-release tablets.
- Uceris is indicated for the induction of remission in patients with active, mild to moderate ulcerative
 colitis.
- Budesonide is also available generically as an <u>oral capsule</u>, a <u>nasal spray</u>, and a <u>nebulizer</u> suspension for inhalation.
 - The oral capsule is approved for the treatment and maintenance of clinical remission of Crohn's disease.
 - The nasal spray is approved for the treatment of seasonal or perennial allergic rhinitis.
 - The nebulized solution for inhalation is approved for the maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.
- Additional branded products containing budesonide include <u>Uceris rectal foam</u>, <u>Pulmicort Flexhaler™</u>, and <u>Symbicort®</u>. Symbicort also contains formoterol.
 - Uceris rectal foam is approved for the induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40 centimeters from the anal verge.
 - Pulmicort Flexhaler is approved for the maintenance treatment of asthma.
 - Symbicort is approved for the treatment of asthma and chronic obstructive pulmonary disease (COPD). Symbicort 160/4.5 is also indicated to reduce exacerbations of COPD.
- Uceris had annual sales of approximately \$196 million in the U.S., according to IMS data as of May 2018.



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