



Renflexis[®] (infliximab-abda) – Expanded indication

- On June 26, 2019, the [FDA approved](#) Samsung Bioepis' [Renflexis \(infliximab-abda\)](#), for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy.
 - Previously, Renflexis was approved for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active UC who have had an inadequate response to conventional therapy.
- Renflexis is also approved to treat Crohn's disease in adult and pediatric patients, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.
- Renflexis is a biosimilar to Janssen's [Remicade[®] \(infliximab\)](#).
- Similar to Remicade, Renflexis carries a boxed warning for serious infections and malignancy.
- The recommended dose of Renflexis for pediatric patients 6 years and older with moderately to severely active UC is 5 mg/kg given as an intravenous induction regimen at 0, 2 and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks.
- Consult the Renflexis drug label for dosing information for all other indications.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.