

Maklumat tambahan indikasi untuk upload pada laman web
Year 2017

Products Approved For Additional Indication (DCA 308 – 26 January 2017)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 REMICADE POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION [Infliximab 100 mg/ vial]	<p>➤ Indication:</p> <p><i><u>Paediatric ulcerative colitis</u></i> <i>Remicade is indicated for treatment of severely active ulcerative colitis, in children and adolescents aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.</i></p> <p>➤ Posology:</p> <p><i>Ulcerative colitis (6 to 17 years)</i> <i>5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Available data do not support further infliximab treatment in paediatric patients not responding within the first 8 weeks of treatment.</i> <i>The safety and efficacy of Remicade have not been studied in children with ulcerative colitis below the age of 6 years. Currently available pharmacokinetic data are described in pharmacokinetic properties' section but no recommendation on a posology can be made in children younger than 6 years.</i></p>	JOHNSON & JOHNSON SDN BHD Lot 3 & 5, Jalan Tandang 46050 Petaling Jaya, Selangor