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Year 2014
Products Approved For Additional Indication (DCA 280 – 18 September 2014)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **HUMIRA SOLUTION FOR INJECTION** [Adalimumab 50mg/ml]	➢ Indication: *Pediatric Crohn's Disease* *Humira is indicated for for the treatment of severe active Crohn's disease in pediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindication for such therapies.* ➢ Posology: *Pediatric Crohn's disease patients < 40kg* *The recommended Humira induction dose regimen for pediatric subjects with severe Crohn's disease is 40mg at Week 0 followed by 20mg at Week 2. In case there is a need for a more rapid response to therapy, the regimen 80mg at Week 0 (dose can be administered as two injections in one day), 40mg at Week 2 can be used, with the awareness that the risk for adverse events maybe higher with use of the higher induction dose.* *After induction treatment, the recommended dose is 20mg every other week via subcutanoues injection. Some subjects who experience insufficient response may benefit from an increase in dosing frequency to 20mgHumira every week.* *Pediatric Crohn's disease patients >40kg* *The recommended Humira induction dose regimen for pediatric subjects with severe Crohn's disease is 80mg at week 0 followed by 40mg at Week 2. In case there is a need for a more rapid response to therapy, the regimen 160mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), 80mg at Week 2 can be used, with the awareness that the risk for adverse events maybe higher with use of the higher induction dose.* *After induction treatment, the recommended dose is 40mg every other week via subcutaneous injection. Some subjects who experience insufficient response may benefit from an increase in dosing frequency to 40mg Humira every week. Continued therapy should be carefully considered in a subject not responding by Week 12.* *There is no relevant use of Humira in children aged below 6 years in this indication.*	**ABBVIE SDN. BHD.** No.24 Jalan Pemaju U1/15 SeksyenU1 HICOM-Glenmarie Industrial Park 40150 Shah Alam, Selangor

2.	2.1 **HUMIRA SOLUTION FOR INJECTION** [Adalimumab 50mg/ml]	➢ Indication: *Polyarticular Juvenile Idiopathic Arthritis* *Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 4 years old who have had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.* ➢ Posology: *<u>Polyarticular Juvenile Idiopathic Arthritis from 4 to 12 years of age</u>* *The recommended dose of Humira for patients with polyarticular juvenile idiopathic, aged 4-12 years, is 24mg/m^2 body surface area up to a maximum single dose of 40mg adalimumab administered every other week via subcutaneous injection. The volume for injection is selected based on the patient's height and weight (Table 1).* <u>Table 1:Humira Dose in Mililitres (ml) by Height and Weight of Children for Polyarticular Juvenile Idiopathic Arthritis</u>	**ABBVIE SDN. BHD.** No.24 Jalan Pemaju U1/15 SeksyenU1 HICOM-Glenmarie Industrial Park 40150 Shah Alam, Selangor

Height (cm)	**Total body weight (kg)**												
	10	**15**	**20**	**25**	**30**	**35**	**40**	**45**	**50**	**55**	**60**	**65**	**70**
80	**0.2**	**0.3**	**0.3**	**0.3**									
90	**0.2**	**0.3**	**0.3**	**0.4**	**0.4**	**0.4**							
100	**0.3**	**0.3**	**0.3**	**0.4**	**0.4**	**0.4**	**0.5**	**0.5**					
110	**0.3**	**0.3**	**0.4**	**0.4**	**0.4**	**0.5**	**0.5**	**0.5**	**0.5**	**0.6**	**0.6**		
120	**0.3**	**0.4**	**0.4**	**0.4**	**0.5**	**0.5**	**0.5**	**0.6**	**0.6**	**0.6**	**0.6**	**0.7**	**0.7**
130		**0.4**	**0.4**	**0.5**	**0.5**	**0.5**	**0.6**	**0.6**	**0.6**	**0.6**	**0.7**	**0.7**	**0.7**
140		**0.4**	**0.4**	**0.5**	**0.5**	**0.6**	**0.6**	**0.6**	**0.7**	**0.7**	**0.7**	**0.7**	**0.8***
150			**0.5**	**0.5**	**0.6**	**0.6**	**0.6**	**0.7**	**0.7**	**0.7**	**0.7**	**0.8***	**0.8***
160			**0.5**	**0.5**	**0.6**	**0.6**	**0.7**	**0.7**	**0.7**	**0.8***	**0.8***	**0.8***	**0.8***
170				**0.6**	**0.6**	**0.6**	**0.7**	**0.7**	**0.8***	**0.8***	**0.8***	**0.8***	**0.8***
180					**0.6**	**0.7**	**0.7**	**0.8***	**0.8***	**0.8***	**0.8***	**0.8***	**0.8***

*** Maximum single dose is 40mg (0.8ml)**

Safety and effectiveness in pediatric patients with Polyarticular JIA less than 4 years have not been established. Limited data are available for Humira treatment in pediatric patients with Polyarticular JIA with a weight below 15 kg.

<u>Polyarticular Juvenile Idiopathic Arthritis from 13 years of age</u>
The recommended dose of humira for patients with polyarticular juvenile idiopathic

		arthritis, aged 13 years and above is 40mg adalimumab administered every other week as single dose via subcutaneous injection. *Available data suggest that clinical response is usually achieved within 12 weeks of treatment. Continued therapy should be carefully reconsidered in a patient not responding within this time period.*	