

**Maklumat tambahan indikasi untuk upload pada laman web  
Year 2016**

**Products Approved For Additional Indication (DCA 304 – 27 September 2016)**

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p><b>1.1 HUMIRA SOLUTION FOR INJECTION</b> [Adalimumab 40mg/0.8 ml]</p>	<p>➤ Indication:</p> <p><i>Axial Spondyloarthritis:</i></p> <p><u>Ankylosing Spondylitis</u> <i>Humira is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.</i></p> <p><u>Non-radiographic Axial Spondyloarthritis (Axial Spondyloarthritis without Radiographic Evidence of AS)</u> <i>Humira is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) but with objective signs of inflammation by elevated CRP and / or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.</i></p> <p>➤ Posology:</p> <p><i>Rheumatoid Arthritis, Psoriatic Arthritis, and Axial Spondyloarthritis (Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis)</i> <i>The recommended dose of Humira of adult patients with rheumatoid arthritis, psoriatic arthritis, or axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis) is 40mg administered every other week as a single dose via subcutaneous injection. Methotrexate, glucocorticoids, salicylates, nonsteroidal anti-inflammatory drugs, analgesics or other DMARDs may be continued during treatment with Humira.</i> <i>In rheumatoid arthritis, some patients not taking concomitant MTX may derive additional benefit from increasing the dosing frequency of Humira to 40 mg every week. (optional)</i></p>	<p><b>ABBVIE SDN BHD</b> 9th Floor Menara Lien Hoe No.8, Persiaran Tropicana Tropicana Golf &amp; Country Resort 47410 Petaling Jaya, Selangor</p>