

Maklumat tambahan indikasi untuk upload pada laman web
Year 2014

Products Approved For Additional Indication (DCA 282 – 4 Disember 2014)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p>CIMZIA 200 mg solution for injection, certolizumab pegol [Certolizumab Pegol 200mg/mL]</p>	<p>➤ Indication:</p> <p><u>Psoriatic arthritis (PsA)</u> <i>Cimzia, in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate.</i></p> <p><i>Cimzia can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.</i></p> <p><u>Ankylosing spondylitis (AS)</u> <i>Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).</i></p> <p>➤ Posology:</p> <p><i>Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Cimzia is indicated.</i> <i>Patients should be given the special alert card.</i></p> <p><u>Loading dose:</u> <i>The recommended starting dose of Cimzia for adult patients is 400mg (given as 2 subcutaneous injection of 200mg each) at week 0, 2 and 4.</i> <i>For rheumatoid arthritis and psoriatic arthritis, MTX should be continued during treatment with Cimzia where appropriate.</i></p>	<p>UCB TRADING (MALAYSIA) SDN BHD Level 21, Suite 21.01 The Gardens South Tower Mid Valley City Lingkaran Syed Putra 59200 Kuala Lumpur</p>

Maintenance dose:

Rheumatoid arthritis

After the starting dose, the recommended dose of Cimzia for adult patients with rheumatoid arthritis is 200mg every 2 weeks. Once clinical response is confirmed, an alternative maintenance dosing of 400mg every 4 weeks can be considered. MTX should be continued during treatment with Cimzia where appropriate.

Psoriatic Arthritis

After the starting dose, the recommended dose of Cimzia for adult patients with psoriatic arthritis is 200mg every 2 weeks. Once clinical response is confirmed, an alternative maintenance dosing of 400mg every 4 weeks can be considered. MTX should be continued during treatment with Cimzia where appropriate.

Ankylosing Spondylitis

After the starting dose, the recommended maintenance dose of Cimzia for adult patients with ankylosing spondylitis is 200mg every 2 weeks or 400mg every 4 weeks.