

Maklumat tambahan indikasi

Year 2018

Products Approved For Additional Indication (DCA 320 – 30 Januari 2018)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 BLINCYTO (BLINATUMOMAB) FOR INJECTION 35 MCG/VIAL [35MCG BLINATUMOMAB]	<p>➤ Indication:</p> <p><i>BLINCYTO is indicated for the treatment of:</i></p> <ul style="list-style-type: none">• <i>Adult patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) [see Dosage and Administration (2.1)].</i>• <i>Pediatric patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) [see Dosage and Administration (2.1)]. Continued approval for this indication may be contingent upon the verification of the results from the confirmatory clinical studies.</i>	<p>ZUELLIG PHARMA SDN BHD No. 15, Persiaran Pasak Bumi, Sek U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor</p>