

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 391, 7 Disember 2023

Products approved for additional indication (DCA 391 – 7 December 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	<p>Yulareb 50mg film-coated tablets [Abemaciclib 50mg]</p> <p>Yulareb 100mg film-coated tablets [Abemaciclib 100mg]</p> <p>Yulareb 150mg film-coated tablets [Abemaciclib 150mg]</p>	<p>INDICATION :</p> <p><u>Advanced or Metastatic Breast Cancer</u></p> <p>YULAREB™ (abemaciclib) is indicated:</p> <ul style="list-style-type: none"> • in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. • in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. <p>POSODOLOGY :</p> <ul style="list-style-type: none"> • When used in combination with fulvestrant, tamoxifen, or an aromatase inhibitor, the recommended dose of YULAREB is 150 mg taken orally twice daily. Refer to the Full Prescribing Information for the recommended dose of the fulvestrant, tamoxifen, or aromatase inhibitor being used. • Pre/perimenopausal women <u>and men</u> treated with the combination of YULAREB plus an aromatase inhibitor should be treated with a gonadotropin-releasing hormone agonist (GnRH) according to current clinical practice standards. • Pre/perimenopausal women treated with the combination of YULAREB plus fulvestrant should be treated with a GnRH agonist according to current clinical practice standards. • Early Breast Cancer: YULAREB should be taken continuously for two years, or until disease recurrence or unacceptable toxicity occurs. • Advanced or metastatic breast cancer: Continue treatment until disease progression or unacceptable toxicity. 	<p>ZUELLIG PHARMA SDN. BHD. No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.</p>