

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 386, 6 Julai 2023

Products approved for additional indication (DCA 386 – 6 July 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	ARCOXIA 30MG TABLET ARCOXIA 60MG TABLET [Etoricoxib 30mg Etoricoxib 60mg]	INDICATION : ARCOXIA is indicated for: <ul style="list-style-type: none">• Chronic low back pain (30 mg and 60 mg only) POSOLOGY : Chronic low back pain The recommended dose is 60 mg once daily. Doses greater than those recommended for each indication have either not demonstrated additional efficacy or have not been studied. Therefore: The dose of chronic low back pain should not exceed 60 mg daily.	ORGANON MALAYSIA SDN. BHD. 39W022, Mercu 2, No. 3, Jalan Bangsar, KL Eco City, 59200 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

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2.	<p>Lonsurf Film-coated Tablet 15 mg/6.14 mg (Trifluridine/Tipiracil)</p> <p>Lonsurf Film-coated Tablet 20 mg/8.19 mg (Trifluridine/Tipiracil)</p> <p>[Trifluridine 15 mg/ Tipiracil Hydrochloride 7.065 mg (equivalent to 6.14 mg of Tipiracil)</p> <p>Trifluridine 20 mg/ Tipiracil Hydrochloride 9.420 mg (equivalent to 8.19 mg of Tipiracil)]</p>	<p>INDICATION :</p> <p>Metastatic Gastric Cancer</p> <p>Lonsurf® is indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.</p> <p>POSODOLOGY :</p> <p>The recommended starting dose of Lonsurf® in adults is 35 mg/m²/dose administered orally twice daily within one hour of completion of morning and evening meals on Days 1 to 5 and Days 8 to 12 of each 28-day cycle as long as benefit is observed or until unacceptable toxicity occurs.</p>	<p>ZUELLIG PHARMA SDN. BHD.</p> <p>No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.</p>

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4.	<p>AUGMENTIN TABLET 625MG</p> <p>[Amoxicillin trihydrate 500mg and potassium clavulanate 125mg]</p>	<p>INDICATION :</p> <p>Removal of the phrase “for twice daily dosing,” from the approved indication.</p> <p>POSOLOGY :</p> <p>Adults and Children over 12 years \geq 40 kg</p> <p>The usual recommended daily dosage is:</p> <table border="1" data-bbox="539 584 1608 871"> <tr> <td data-bbox="539 584 880 687">Mild - Moderate infections</td> <td data-bbox="880 584 1608 687">One AUGMENTIN 625 mg tablet every 12 hours.</td> </tr> <tr> <td data-bbox="539 687 880 871">Severe infections</td> <td data-bbox="880 687 1608 871"> One AUGMENTIN 1 g tablet every 12 hours <u>OR</u> <u>One AUGMENTIN 625 mg tablet every 8 hours.</u> </td> </tr> </table> <p>Renal Impairment</p> <p><u>Dosage adjustments are based on the maximum recommended level of amoxicillin.</u></p> <p>No adjustment in dose is required in patients with creatinine clearance (CrCl) greater than 30 mL/min. The AUGMENTIN 1g tablet should only be used in patients with a creatinine clearance (CrCl) rate of more than 30 mL/min.</p>	Mild - Moderate infections	One AUGMENTIN 625 mg tablet every 12 hours.	Severe infections	One AUGMENTIN 1 g tablet every 12 hours <u>OR</u> <u>One AUGMENTIN 625 mg tablet every 8 hours.</u>	<p>GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.</p> <p>HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.</p>
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