

**Maklumat tambahan indikasi untuk upload pada laman web
Year 2014**

Products Approved For Additional Indication (DCA 284 – 29 January 2015)

| NO | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER | | | | | | | | | |
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| 1. | <p>1.1 PARIET TABLET 10MG</p> <p>1.2 PARIET TABLET 20MG</p> <p>[Rabeprazole sodium]</p> | <p>➤ Indication:</p> <p><i>Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence in Adults</i></p> <p><i>Pariet® in combination with amoxicillin and clarithromycin as a three drug regimen, is indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history within the past 5 years) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.</i></p> <p><i>In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.</i></p> <p>➤ Posology:</p> <p><i>Helicobacter pylori Eradication to Reduce the Risk of Duodenal ulcer Recurrence in Adults</i></p> <p>THREE DRUG REGIMEN^a</p> <table border="1" data-bbox="852 1057 1577 1219"> <tbody> <tr> <td><i>PARIET</i></td> <td><i>20mg</i></td> <td><i>Twice Daily for 7 Days</i></td> </tr> <tr> <td><i>Amoxicillin</i></td> <td><i>1000mg</i></td> <td><i>Twice Daily for 7 Days</i></td> </tr> <tr> <td><i>Clarithromycin</i></td> <td><i>500mg</i></td> <td><i>Twice Daily for 7 Days</i></td> </tr> </tbody> </table> <p><i>All three medications should be taken twice daily with the morning and evening meals.</i></p> <p>^a <i>It is important that patients comply with the full 7-day regimen.</i></p> | <i>PARIET</i> | <i>20mg</i> | <i>Twice Daily for 7 Days</i> | <i>Amoxicillin</i> | <i>1000mg</i> | <i>Twice Daily for 7 Days</i> | <i>Clarithromycin</i> | <i>500mg</i> | <i>Twice Daily for 7 Days</i> | <p>EISAI (MALAYSIA) SDN BHD</p> <p>Lot 6.1, 6th.Floor Menara Lien Hoe No. 8, Persiaran Tropicana 47410 Petaling Jaya, Selangor</p> |
| <i>PARIET</i> | <i>20mg</i> | <i>Twice Daily for 7 Days</i> | | | | | | | | | | |
| <i>Amoxicillin</i> | <i>1000mg</i> | <i>Twice Daily for 7 Days</i> | | | | | | | | | | |
| <i>Clarithromycin</i> | <i>500mg</i> | <i>Twice Daily for 7 Days</i> | | | | | | | | | | |

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| 2. | <p>2.1 EYLEA 40MG/ML SOLUTION FOR INJECTION IN VIAL</p> <p>2.1 EYLEA 40MG/ML SOLUTION FOR INJECTION IN PREFILLED SYRINGE</p> <p>[Aflibercept 40mg/mL]</p> | <p>➤ Indication:</p> <p><i>Visual impairment due to diabetic macular edema (DME)</i></p> <p>➤ Posology:</p> <p><i>Diabetic macular edema (DME):</i> <i>The recommended dose for Eylea is 2mg aflibercept (equivalent to 50 microliters) administered by intravitreal injection monthly for the first 5 consecutive doses, followed by one injection every 2 months. There is no requirement for monitoring between injections.</i></p> <p><i>After the first 12 months of treatment with Eylea, the treatment interval may be extended based on visual and anatomic outcomes. The schedule for monitoring should be determined by the treating physician.</i></p> <p><i>If visual and anatomic outcomes indicate that the patient is not benefiting from continued treatment, Eylea should be discontinued.</i></p> | <p>BAYER CO. (MALAYSIA) SDN. BHD. T1-14 Jaya 33, No.3 Jalan Semangat, Seksyen 13 46200 Petaling Jaya, Selangor</p> |
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