

**Maklumat tambahan indikasi
Year 2017**

Products Approved For Additional Indication (DCA 314 – 3 August 2017)

| NO | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
|----|--|--|---|
| 1. | 1.1 CYCLOGEST 400MG PESSARIES [PROGESTERONE 400MG] | <p>➤ Indication:</p> <p><i>Luteal phase support as part of an Assisted Reproductive Technology (ART) treatment for women. (Only for Cyclogest 400mg pessary)</i></p> <p>➤ Posology:</p> <p><i>For luteal phase support as part of an ART treatment: 400 mg administered vaginally twice a day starting at oocyte retrieval. The administration of Cyclogest should be continued for 38 days, if pregnancy has been confirmed.</i></p> <p><i>Use in special populations: There is no experience with use of Cyclogest in patients with impaired liver or renal function.</i></p> <p><i>Paediatric population: There is no relevant use of Cyclogest in the paediatric population.</i></p> <p><i>Elderly: No clinical data have been collected in patients over age of 65.</i></p> | ACTAVIS SDN BHD Lot No. 8F-1B, 8th Floor Tower 4 @ PFCC, Jalan Puteri 1/2 Bandar Puteri 47100 Puchong, Selangor |