

Maklumat tambahan indikasi

Year 2020

Products Approved For Additional Indication (DCA 351 – 3 Disember 2020)

	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER						
1.	<p><b>1.1 FluQuadri Quadrivalent Influenza Vaccine, 0.5 ml</b> [Each 0.5 ml dose contains 15 µg HA of the following strains: A(H1N1), A(H3N2), B/Victoria, B/Yamagata]</p>	<p>➤ Posology:</p> <p><i>For intramuscular use only</i></p> <p><b>Dose and Schedule</b> <i>The dose and schedule for FluQuadri are presented in Table 1.</i></p> <p><i>Table 1: Dose and schedule for FluQuadri:</i></p> <table border="1" data-bbox="786 667 1700 783"> <thead> <tr> <th>Age</th> <th>No. of Doses</th> </tr> </thead> <tbody> <tr> <td>6 months through 8 years</td> <td>1* or 2** doses of 0.5 ml</td> </tr> <tr> <td>9 years and older</td> <td>1 dose of 0.5 ml</td> </tr> </tbody> </table> <p>* <i>Eligible children &lt; 9 years of age who have properly received one or more doses of seasonal influenza vaccine in the past are recommended to receive one dose per season thereafter.</i></p> <p>** <i>Previously unvaccinated children 6 months through 8 years of age require 2 doses of seasonal influenza vaccine with an interval of 4 weeks.</i></p>	Age	No. of Doses	6 months through 8 years	1* or 2** doses of 0.5 ml	9 years and older	1 dose of 0.5 ml	<p><b>SANOFI-AVENTIS (MALAYSIA) SDN. BHD.</b> Unit TB-18-1, Level 18, Tower B, Plaza 33 No.1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor</p>
Age	No. of Doses								
6 months through 8 years	1* or 2** doses of 0.5 ml								
9 years and older	1 dose of 0.5 ml								
2.	<p><b>2.1 Vectibix 100mg Concentrate For Solution For Infusion</b> [Panitumumab 20mg/ml]</p>	<p>➤ <i>Indication:</i></p> <p><i>Vectibix is indicated for the treatment of adult patients with wild-type RAS metastatic colorectal cancer (mCRC):</i></p> <ul style="list-style-type: none"> <li><i>In first-line in combination with FOLFOX or FOLFIRI.</i></li> </ul>	<p><b>AMGEN BIOPHARMACEUTICALS MALAYSIA SDN BHD</b> Suite 9.01, Level 9, Menara Summit Persiaran Kewajipan USJ 1, UEP 47600 Subang Jaya, Selangor</p>						

3.	<p><b>3.1 Lusefi 2.5mg film-coated tablet</b> [Luseogliflozin hydrate 2.575mg (equivalent to luseogliflozin 2.5mg)]</p> <p><b>3.2 Lusefi 5mg film-coated tablet</b> [Luseogliflozin hydrate 5.150mg (equivalent to luseogliflozin 5mg)]</p>	<p>➤ <i>Indication:</i></p> <p><u><i>Add-on combination therapy with insulin preparations</i></u> <i>In combination with insulin preparations in adult patients with type 2 diabetes mellitus to improve glycaemic control when diet and exercise plus monotherapy does not provide adequate glycaemic control.</i></p>	<p><b>HOE PHARMACEUTICALS SDN. BHD.</b> Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor</p>
4.	<p><b>4.1 Imbruvica 140mg Capsules</b> [Ibrutinib 140mg]</p>	<p>➤ <i>Indication:</i> <i>IMBRUVICA as a single agent or in combination with rituximab or obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) (see section 5.1).</i></p> <p>➤ <i>Posology:</i></p> <p><i>Chronic lymphocytic leukaemia</i></p> <p><i>The recommended dose for the treatment of CLL, either as a single agent or in combination, is 420 mg (three capsules) once daily (for details of the combination regimen, see section 5.1).</i></p> <p><i>Treatment should continue until disease progression or no longer tolerated by the patient.</i></p> <p><i>When administering IMBRUVICA in combination with anti-CD20 therapy, it is recommended to administer IMBRUVICA prior to anti-CD20 therapy when given on the same day.</i></p>	<p><b>JOHNSON &amp; JOHNSON SDN. BHD.</b> Lot 3 &amp; 5, Jalan Tandang 46050 Petaling Jaya, Selangor</p>