

Maklumat tambahan indikasi

Year 2019

Products Approved For Additional Indication (DCA 333 – 4 April 2019)

N O	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p>1.1 <b>BYDUREON 2mg powder and solvent for prolonged-release suspension for injection</b> [Exenatide 2 mg]</p>	<p>➤ Indication:</p> <p><i>BYDUREON is indicated in adults 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose-lowering medicinal products when the therapy in use, together with diet and exercise, does not provide adequate glycaemic control (see section 4.4, 4.5 and 5.1 for available data on different combinations).</i></p> <p><i>Limitations of Use:</i> <i>BYDUREON is not recommended as first-line therapy for patients who have inadequate glycaemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumour findings to humans.</i></p> <p><i>BYDUREON is not a substitute for insulin. BYDUREON is not indicated for use in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.</i></p> <p><i>The concurrent use of BYDUREON with insulin has not been studied and is not recommended.</i></p> <p><i>BYDUREON is an extended-release formulation of exenatide. BYDUREON should not be used with other products containing the active ingredient exenatide.</i></p> <p><i>BYDUREON has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.</i></p>	<p><b>ASTRAZENECA SDN. BHD.</b> Level 11 &amp; 12, Nucleus Tower No. 10, Jalan PJU 7/6 Mutiara Damansara 47800 Petaling Jaya, Selangor</p>

2.	<p><b>2.1 Forxiga 5mg Film-Coated Tablet</b> [Dapagliflozin propanediol 6.150mg, equivalent to dapagliflozin 5mg]</p> <p><b>2.2 Forxiga 10mg Film-Coated Tablet</b> [Dapagliflozin propanediol 12.30mg, equivalent to dapagliflozin 10mg]</p>	<p>➤ Indication:</p> <p><i>Forxiga is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as:</i></p> <p><i>Monotherapy</i> <i>When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance.</i></p> <p><i>Add-on combination therapy</i> <i>In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations).</i></p>	<p><b>ASTRAZENECA SDN. BHD.</b> Level 11 &amp; 12, Nucleus Tower No. 10, Jalan PJU 7/6 Mutiara Damansara 47800 Petaling Jaya, Selangor</p>
3.	<p><b>3.1 Xigduo XR Tablet 10/1000mg</b> [Dapagliflozin propanediol 10mg &amp; metformin hydrochloride 1000mg]</p> <p><b>3.2 Xigduo XR Tablet 5/1000mg</b> [Dapagliflozin propanediol 5mg &amp; metformin hydrochloride 1000mg]</p> <p><b>3.3 Xigduo XR Tablet 10/500mg</b> [Dapagliflozin propanediol 10mg &amp; metformin hydrochloride 500mg]</p>	<p>➤ Indication:</p> <p><i>XIGDUO XR is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate (see section 5.1 Pharmacodynamic properties – Clinical trials and 4.4 Special warnings and precautions for use for available data on the combination therapy).</i></p>	<p><b>ASTRAZENECA SDN. BHD.</b> Level 11 &amp; 12, Nucleus Tower No. 10, Jalan PJU 7/6 Mutiara Damansara 47800 Petaling Jaya, Selangor</p>