

Maklumat tambahan indikasi untuk upload pada laman web

Year 2012

Products Approved For Additional Indication (DCA 253 – 28 JUN 2012)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p>1.1 Onglyza Tablet 2.5mg [Saxagliptin hydrochloride 2.79mg (equivalent to saxagliptin 2.5mg)]</p> <p>1.2 Onglyza Tablet 5mg [Saxagliptin hydrochloride 5.58mg (equivalent to saxagliptin 5mg)]</p>	<p>➤ Indication:</p> <p>ONGLYZA is indicated in adult patients with type 2 diabetes mellitus to improve glycaemic control:</p> <ul style="list-style-type: none"> • In combination with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control <p>➤ Posology:</p> <ul style="list-style-type: none"> - No change to posology - Addition of the paragraph below: <p><i>Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin</i></p> <p>When ONGLYZA is used in combination with an insulin secretagogue (e.g., sulfonylurea) or with insulin, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycaemia.</p>	<p>AstraZeneca Sdn Bhd, Level 12, Surian Tower, 1 Jalan PJU 7/3, Mutiara Damansara, 47810 Petaling Jaya, Selangor.</p>
2.	<p>2.1 Taxotere 20mg/0.5ml vial [20mg docetaxel trihydrate]</p> <p>2.2 Taxotere 80mg/2ml vial [80mg docetaxel trihydrate]</p>	<p>➤ Indication:</p> <p>Breast cancer</p> <ul style="list-style-type: none"> • TAXOTERE (docetaxel) in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with → Operable node-negative breast cancer <p>For patients with operable node-negative breast cancer, adjuvant treatment should be restricted to patients eligible to receive chemotherapy according</p>	<p>Sanofi-Aventis (Malaysia) Sdn Bhd 8th Floor, PNB Damansara, No, 19, Lorong Dungun, Damansara Heights, 50490 Kuala Lumpur.</p>

to internationally established criteria for primary therapy of early breast cancer.

➤ Posology:

- Breast cancer

In the adjuvant treatment of operable node-positive and node-negative breast cancer, the recommended dose of docetaxel is 75 mg/m² administered 1-hour after doxorubicin 50 mg/m² and cyclophosphamide 500 mg/m² every 3 weeks for 6 cycles. For the treatment of patients with locally advanced or metastatic breast cancer, the recommended dosage of docetaxel is 100 mg/m² in monotherapy. In first-line treatment, docetaxel 75 mg/m² is given in combination therapy with doxorubicin (50 mg/m²).