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Year 2015
Products Approved For Additional Indication (DCA 288 – 25 Mei 2015)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **ERBITUX 5MG/ML SOLUTION FOR INFUSION** [Cetuximab 5 mg/mL]	➢ Indication: *Erbitux is indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer* • *in combination with irinotecan-based chemotherapy,* • *in first-line in combination with FOLFOX,* • *as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan.* *Erbitux is indicated for the treatment of patients with squamous cell cancer of the head and neck* • *in combination with radiation therapy for locally advanced disease,* • *in combination with platinum-based chemotherapy for recurrent and/or metastatic disease.* ➢ Posology: *Posology and method of administration* *Erbitux must be administered under the supervision of a physician experienced in the use of antineoplastic medicinal products. Close monitoring is required during the infusion and for at least 1 hour after the end of the infusion. Availability of resuscitation equipment must be ensured.* *<u>Posology:</u>* *Prior to the first infusion, patients must receive premedication with an antihistamine and a corticosteroid at least 1 hour prior to administration of cetuximab. This premedication is recommended prior to all subsequent infusions.* *In all indications, Erbitux is administered once a week. The initial dose is 400 mg cetuximab per m^2 body surface area. All subsequent weekly doses are 250 mg cetuximab per m^2 each.*	**MERCK SDN. BHD.** Level 3, Menara Sunway Annexe Jalan Lagoon Timur, Bandar Sunway 46150 Petaling Jaya, Selangor

Colorectal cancer
In patients with metastatic colorectal cancer, cetuximab is used in combination with chemotherapy or as a single agent (see Pharmacodynamic properties). Evidence of wild-type RAS (KRAS and NRAS) status is required before initiating treatment with Erbitux. Mutational status should be determined by an experienced laboratory using validated test methods for detection of KRAS (exons 2, 3, and 4) and NRAS (exons 2, 3, and 4) mutations (see Special warnings and precautions for use and Pharmacodynamic properties).

For the dosage or recommended dose modifications of concomitantly used chemotherapeutic agents, refer to the product information for these medicinal products. They must not be administered earlier than 1 hour after the end of the cetuximab infusion.

It is recommended that cetuximab treatment be continued until progression of the underlying disease.

Squamous cell cancer of the head and neck
In patients with locally advanced squamous cell cancer of the head and neck, cetuximab is used concomitantly with radiation therapy. It is recommended to start cetuximab therapy one week before radiation therapy and to continue cetuximab therapy until the end of the radiation therapy period.
In patients with recurrent and/or metastatic squamous cell cancer of the head and neck, cetuximab is used in combination with platinum-based chemotherapy followed by cetuximab as maintenance therapy until disease progression (see Pharmacodynamic properties). Chemotherapy must not be administered earlier than 1 hour after the end of the cetuximab infusion.

Special populations
Only patients with adequate renal and hepatic function have been investigated to date (see Special warnings and precautions for use).
Cetuximab has not been studied in patients with pre-existing haematological disorders (see section Special warnings and precautions for use).
No dose adjustment is required in older people, but the

		experience is limited in patients 75 years of age and above. *<u>Method of administration</u>* *Erbitux 5 mg/mL is administered intravenously with an infusion pump, gravity drip or a syringe pump (for handling instructions, see Special precautions for disposal and other handling).* *The initial dose should be given slowly and speed of infusion must not exceed 5 mg/min (see Special warnings and precautions for use). The recommended infusion period is 120 minutes. For the subsequent weekly doses, the recommended infusion period is 60 minutes. The infusion rate must not exceed 10 mg/min.* *<u>Paediatric population</u>* *There is no experience in children (see Special warnings and precautions for use).*	