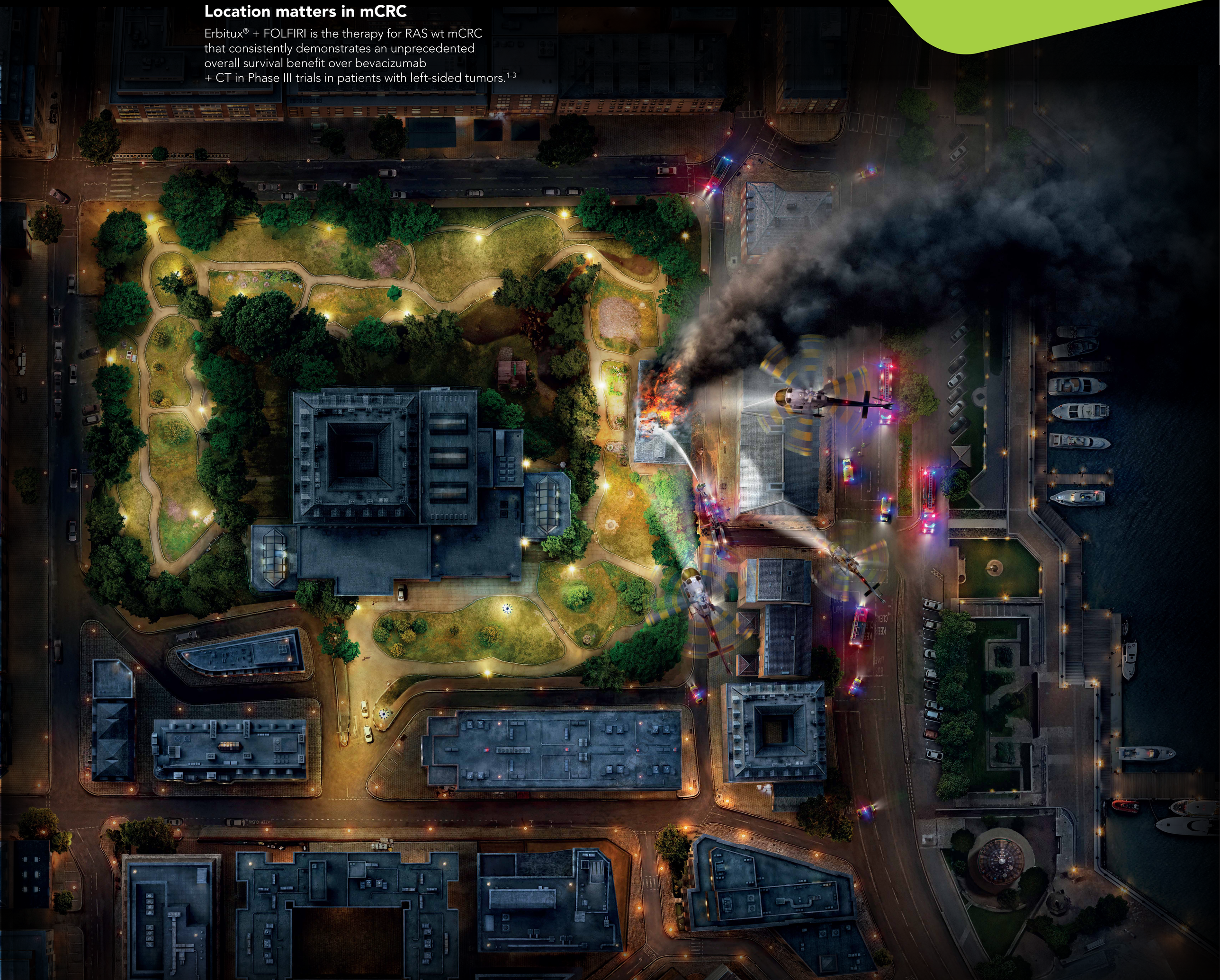
WHAT THEY NEED, WHERE THEY NEED IT

Location matters in mCRC

Erbitux® + FOLFIRI is the therapy for RAS wt mCRC that consistently demonstrates an unprecedented overall survival benefit over bevacizumab + CT in Phase III trials in patients with left-sided tumors.[1-3]



Erbitux® iis 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 or continuous infusional 5-fluorouracil/folinic acid plus oxaliplatin and as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan[4]

CT: chemotherapy; FOLFIRI: folinic acid, fluorouracil and irinotecan; FOLFOX: folinic acid, fluorouracil and oxaliplatin; RAS wt mCRC: RAS wild-type metastatic colorectal cancer.

References: 1. J.W. *Holch et al. / European Journal of Cancer* 70 (2017): 87-98. **2.** Annals of Oncology 28:1713-1729, 2017. **3.** Tejpar S *et al. JAMA Oncol* 2016; epub 10 Oct 2016. **4.** Erbitux® SmPC, April 2014

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา ใบอนุญาตโฆษณาเลขที่ ฆศ.757/2561 เลขทะเบียนยา 1C 12/53 (NB) TH-ERBMCRC-00010

Erbitux® 5 mg/ml
Active ingredient: Cetuximab
Composition Each ml of the solution for infusion contains 5 mg cetuximab as active substance. Each vial contains 20 ml . Excipients: sodium chloride, glycine, polysorbate 80, citric acid monohydrate, sodium hydroxide, water for injections. **Properties** Mechanism of action The Epidermal Growth Factor Receptor (EGFR) is part of signalling pathways involved in the control of cell survival, cell cycle progression, angiogenesis, cell migration and cellular invasion/metastasis. Cetuximab is a chimeric monoclonal IgG1 antibody that is specifically directed against the EGFR. It binds to the EGFR with an approxi -mately 5- to 10 fold higher affinity than endogenous ligands and blocks the receptor's function. It induces the internalisation of EGFR and may thereby lead to down regulation of EGFR. Cetuximab also targets cytotoxic immune effector cells towards EGFR-expressing tumour cells (antibody dependent cell-mediated cytotoxicity, ADCC). The protein product of the proto-oncogene RAS (rat sarcoma) is a central down-stream signal-transducer of EGFR. In tumours, activation of RAS by EGFR contributes to EGFR-mediated increased proliferation, survival and the production of pro-angiogenic factors. RAS is one of the most frequently activated family of oncogenes in human cancers. Mutations of RAS genes at certain hot-spots on exons 2, 3 and 4 result in constitutive activation of RAS proteins independently of EGFR signalling. **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 or continuous infusional 5-fluorouracil/folinic acid plus oxaliplatin (for details, see section Properties) • 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. **Contraindications** Erbitux® is contraindicated in patients with known severe (grade 3 or 4; U.S. National Cancer Institute – Common Terminology Criteria for Adverse Events; CTCAE) hypersensitivity reactions to cetuximab. The combination of Erbitux® with oxaliplatin-containing chemo therapy is contraindicated for patients with mutant RAS metastatic colorectal cancer (mCRC) based on a commercially available test. Pregnancy and lactation It is strongly recommended that Erbitux® be given during pregnancy or to any woman not employing adequate contraception only if the potential benefit justifies a potential risk for the foetus. It is recommended that women do not breast-feed during treatment with Erbitux® and for two months after the last dose, because it is not known whether Erbitux® is excreted in breast milk. **Adverse effects** Very commons adverse effects are Skin reactions, Hypomagnesaemia, ld or moderate infusion-related reactions* (see Special Warnings and Precautions); mucositis, in some cases severe, Mucositis may lead to epistaxis, Increase in liver enzyme levels (ASAT, ALAT, AP) Commons adverse effects are Headache, Conjunctivitis, Diarrhoea, nausea, vomiting, Dehydration, in particular secondary to diarrhoea or mucositis; hypocalcaemia; anorexia which may lead to weight decrease, Severe infusion-related reactions, in some cases with fatal outcome, fatigue. Skin reactions Skin reactions may develop in more than 80% of patients and mainly present as acne-like rash and/or, less frequently, as pruritus, dry skin, desquamation, hypertrichosis, or nail disorders (e.g. paronychia). Approximately 15% of the skin reactions are severe, including single cases of skin necrosis. The majority of skin reactions develop within the first three weeks of therapy. They generally resolve, without sequelae, over time following cessation of treatment if the recommended adjustments in dose regimen are followed. Skin lesions induced by Erbitux® may predispose patients to superinfections (e.g. with S. aureus), which may lead to subsequent complications, e.g. cellulitis, erysipelas, or, potentially with fatal outcome, staphylococcal scalded skin syndrome, necrotising fasciitis or sepsis. **Dosage and Administration** Prior to the first infusion, patients must receive premedication with an antihistamine and a corticosteroid at least 1 hour prior to administration of Erbitux® . This premedication is recom-mended prior to all subsequent infusions. In all indications, Erbitux® is administered once a week. The very first dose is 400 mg Erbitux® per m^2 body surface area. All subsequent weekly doses are 250 mg per m^2 each. The initial dose should be given slowly and speed of infusion must not exceed 5 mg/min. 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. **Overdose** There is limited experience with single doses higher than 400 mg/m^2 body surface area to date or weekly admini strations of doses higher than 250 mg/m^2 body surface area. **Storage and Stability** Store in a refrigerator (2ºC - 8ºC). Do not use after the expiry date. **Keep medicines out of the reach of children.** Chemical and physical in-use stability of Erbitux® 5 mg/ml has been demonstrated for 48 hours at 25°C, if the solution is prepared as described above. Erbitux® does not contain any antimicrobial preservative or bacteriostatic agent. Use immediately after opening. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C - 8°C. **Presentation** 20 ml of solution for infusion in a vial. One vial per pack.

ERBITUX® CETUXIMAB

MERCK