

ERBITUX® (5 mg/ml cetuximab, chimeric monoclonal IgG₁ antibody) I: For the treatment of patients with EGFR (epidermal growth factor receptor) expressing RAS wild-type metastatic colorectal cancer: a) in combination with FOLFIRI or FOLFOX; b) as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy or who are intolerant to irinotecan. In combination with radiation therapy for the treatment of patients with locally advanced squamous cell cancer of the head and neck. In combination with cisplatin and 5-fluorouracil for the treatment of patients with recurrent and/or metastatic squamous cell cancer of the head and neck. **PO:** The very first dose is 400 mg cetuximab per m² body surface area. Subsequent weekly doses 250 mg/m². Premedication with an antihistamine and a corticosteroid. Instructions for administration are to be strictly adhered to. **CI:** Known severe hypersensitivity reactions to cetuximab or to any of the excipients; pregnancy and lactation; in combination with an oxaliplatin-containing chemotherapy in mCRC-patients with RAS mutations or with an unknown RAS mutation status. **W:** Severe infusion-related, including anaphylactic reactions are possible and usually occur during and up to 1 hour after the end of the initial Erbitux infusion but may occur after several hours or with subsequent infusions. They may include symptoms such as bronchospasm, urticaria, hypotension, hypertension, loss of consciousness or shock, in rare cases angina pectoris, myocardial infarction or cardiac arrest. These reactions require immediate and permanent discontinuation of cetuximab therapy and a symptomatic treatment. Interstitial lung disorders; severe skin reactions, especially in combination with chemotherapy; electrolyte disturbances such as hypomagnesaemia, hypocalcaemia or hypokalaemia; neutropenia; cardiovascular disorders, eye disorders, colorectal cancer patients with RAS mutated tumours. **IA:** None known. **UE:** Very common: Hypomagnesaemia; mucositis; increase in AST, ALT and AP; skin reactions (mainly acne-like rash); mild or moderate infusion-related reactions. Common: Hypocalcaemia; anorexia; dehydration; headache; conjunctivitis; diarrhea; nausea; vomiting; epistaxis; pruritus; dry skin; desquamation; hypertrichosis or nail disorders; in combination with fluoropyrimidines hand-foot syndrome; severe infusion-related reactions; fatigue. **P:** 1 vial of 20 ml (100 mg cetuximab) and 100 ml (500 mg cetuximab). [A]. For further information, see www.swissmedicinfo.ch. v01