Vinorelbine medac 20 mg / 30 mg / 80 mg soft capsules
Qualitative and quantitative composition: Each soft capsule contains vinorelbine tartrate equivalent to 20 mg (30 mg; 80 mg) vinorelbine. *Excipients:* Each soft capsule containing 20 mg (30 mg; 80 mg) vinorelbine contains 10.54 mg (15.96 mg; 29.35 mg) sorbitol and 5 mg (7.5 mg; 20 mg) ethanol. Purified water, glycerol, macrogol 400, gelatin, glycerol, titanium dioxide (E171). Vinorelbine 20 mg and 80 mg Soft Capsules: Iron oxide yellow (E172); Vinorelbine 30 mg Soft Capsules: Iron red oxide (E172). Printing ink (Nonvolatile component-shellac glaze, black iron oxide (E172), propylene glycol), medium chain triglycerides. **Therapeutic indications:** Non-small cell lung cancer, advanced breast cancer. **Posology and method of administration:** As a single agent 60 mg/m² of body surface area, administered once weekly (first three administrations). Beyond the third administration, it is recommended to increase the dose to 80 mg/m² once weekly except in those patients for whom the neutrophil count dropped once below 500/mm³ or more than once between 500 and 1000/mm³ during the first three administrations at 60 mg/m². For combination regimens, the dose and schedule will be adapted to the treatment protocol. Even for patients with BSA ≥ 2 m² the total dose should never exceed 120 mg per week at 60 mg/m² and 160 mg per week at 80 mg/m². Vinorelbine Soft Capsules must be given strictly by the oral route. They should be swallowed with water without chewing or sucking the capsule because the liquid inside is an irritant and may be harmful if it comes into contact with skin, eyes or mucosa. It is recommended to take the capsule with some food. **Contraindications:** Known hypersensitivity to vinorelbine or other vinca alkaloids or to any of the constituents; disease significantly affecting absorption; previous significant surgical resection of stomach or small bowel; neutrophil count < 1500/mm³ or severe infection current or recent (within 2 weeks); platelet count < 100000/mm³; lactation; patients requiring long-term oxygen therapy; in combination with yellow fever vaccine. **Undesirable effects:** *Infections, infestations:* Very commonly bacterial, viral or fungal infections without neutropenia at different sites. Common bacterial, viral or fungal infections resulting from bone marrow depression and/or immune system compromise (neutropenic infections) are usually reversible with an appropriate treatment. Frequency not known: Neutropenic sepsis, complicated septicaemia, sometimes fatal; severe sepsis sometimes with other organ failure; septicaemia. *Blood, lymphatic system:* Very commonly bone marrow depression resulting mainly in neutropenia is reversible and the dose limiting toxicity, leucopenia, anaemia, thrombocytopenia. Commoly neutropenia associated with fever over 38 °C including febrile neutropenia. Frequency not known: Thrombocytopenia, pancytopenia. *Endocrine:* Frequency not known: Inappropriate antidiuretic hormone secretion (SIADH). *Metabolism, nutrition:* Very commonly anorexia. Frequency not known: Severe hyponatraemia. *Psychiatric:* Commonly insomnia. *Nervous system:* Very commonly neurosensory disorders were generally limited to loss of tendon reflexes and infrequently severe. Commonly neuromotor disorders, headache, dizziness, taste disorders. Uncommon ataxia. Frequency not known: Posterior reversible encephalopathy syndrome. *Eye:* Commonly visual impairment. *Cardiac:* Uncommon heart failure, cardiac dysrhythmia. Frequency not known: Myocardial infarction in patients with cardiac medical history or cardiac risk factors. *Vascular:* Commonly arterial hypertension, arterial hypotension. *Respiratory, thoracic, mediastinal:* Commonly dyspnoea, cough. Frequency not known: Pulmonary embolism. *Gastrointestinal:* Very commonly nausea, vomiting; supportive treatment (such as oral setrons) may reduce the occurrence of nausea and vomiting; diarrhoea, stomatitis, abdominal pain, constipation; prescription of laxatives may be appropriate in patients with prior history of constipation and /or who received concomitant treatment with morphine or morphine-mimetics; gastric disorders. Commonly oesophagitis, dysphagia. Uncommonly paralytic ileus (exceptionally fatal) - treatment may be resumed after recovery of normal bowel mobility. Frequency not known: Gastrointestinal bleeding. *Hepatobiliary:* Commonly hepatic disorders. Frequency not known: Transient elevations of liver function tests. *Skin, subcutaneous tissues:* Very commonly alopecia usually mild in nature may occur. Commonly skin reactions. *Musculoskeletal, connective tissues*: Commonly arthralgia including jaw pain, myalgia. *Renal, urinary:* Commonly dysuria, other genitourinary symptom. *General, administration site conditions:* Very commonly fatigue/malaise, fever. Commonly pain including pain at the tumour site, chills. *Investigations:* Very commonly weight loss. Commonly weight gain. **Legal classification**: POM (prescription only medicine). **Marketing authorisation holder:** medac GmbH Theaterstraße 6; 22880 Wedel, Germany. **Date of revision of text**: 05/2023
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