Sodiofolin 50 mg/ml, solution for injection/infusion
Qualitative and quantitative composition: Sodiofolin contains 54.65 mg/ml disodium folinate equivalent to 50 mg/ml folinic acid. 2 ml (4ml; 6ml; 8ml; 10ml; 18ml) of solution contain 109.3mg (218.6mg; 327.9mg; 437.2mg; 546.5mg; 983.7mg) disodium folinate equivalent to 100 (200; 300; 400; 500; 900) mg folinic acid. *Excipients:* Sodium hydroxide, hydrochloric acid, water for injection. **Therapeutic indications:** Disodium folinate is indicated**:** - to diminish the toxicity and counteract the action of folic acid antagonists such as methotrexate in cytotoxic therapy and overdose in adults and children. In cytotoxic therapy, the procedure is commonly known as "Folinate Rescue"; - in combination with 5-fluorouracil in cytotoxic therapy. *Note:* Persistently high serum methotrexate levels may also be expected in low-dose methotrexate therapy particularly in pleural effusions, ascites, renal insufficiency, and inadequate fluid intake during methotrexate therapy. **Posology and method of administration:** Sodiofolin is administered intravenously, either undiluted by injection or by infusion after dilution. The combined use of disodium folinate and fluorouracil is reserved for physicians experienced in the combination of folinates with 5-fluorouracil in cytotoxic therapy. Different regimes and different dosages are used, without any dosage having been proven to be the optimal one. **Contraindications:** Known hypersensitivity to disodium folinate or any of the excipients. The combination of disodium folinate with fluorouracil is not indicated in existing contraindications against fluorouracil, in particular breastfeeding, severe diarrhoea. Therapy with disodium folinate combined with fluorouracil must not be initiated or continued in patients who have symptoms of gastrointestinal toxicity of any severity until those symptoms have completely resolved. Patients with diarrhoea must be monitored with particular care until the diarrhoea has resolved, as rapid clinical deterioration leading to death can occur. Regarding the use of folinic acid with methotrexate or 5 fluorouracil during pregnancy and breastfeeding, see summaries of product characteristics for methotrexate- and 5 fluorouracil-containing medicinal products. Disodium folinate is not suitable for the treatment of pernicious anaemia or other anaemias due to Vitamin B12 deficiency. Although haematological remissions may occur, the neurological manifestations remain progressive. **Undesirable effects:** *All therapeutic indications: Immune system:* Very rarely allergic reactions - sensitisation, including anaphylactoid reactions and urticaria. *Psychiatric:* Rarely insomnia, agitation and depression after high doses. *Nervous system:* Rarely increase in the frequency of attacks in epileptics. *Gastrointestinal:* Rarely gastrointestinal disorders after high doses. *General, administration site:* Uncommonly fever after administration as solution for injection. *Combination therapy with 5 fluorouracil:* Disodium folinate enhances the toxicity of 5 fluorouracil. Generally, the safety profile depends on the applied regimen of 5 fluorouracil. *Blood, lymphatic system:* Bone marrow failure, including fatal cases. *Metabolism, nutrition:* Hyperammonaemia. *Skin, subcutaneous tissue:* Palmar-plantar erythrodysaesthesia. *General, administration site:* Mucositis, including stomatitis and cheilitis. Fatalities as result of mucositis. *Gastrointestinal:* Vomiting, nausea; diarrhoea with higher grades of toxicity, dehydration resulting in hospital admission for treatment and even death. **Legal classification:** POM (prescription only medicine). **Marketing authorisation holder:** medac GmbH, Theaterstraße 6; 22880 Wedel, Germany. **Date of revision of text:** 3/2024
Sodiofolin 50 mg/ml has been authorized in Germany, Kazakhstan, Russia, United Kingdom (not all strengths are authorized in all countries)