Gliolan® 30 mg/ml powder for oral solution. **Qualitative and quantitative composition:** One bottle contains 1.17 g of 5-aminolevulinic acid (5-ALA), corresponding to 1.5 g 5-aminolevulinic acid hydrochloride (5-ALA HCl). One ml of reconstituted solution contains 23.4 mg of 5-aminolevulinic acid, corresponding to 30 mg 5-aminolevulinic acid hydrochloride (5-ALA HCl). **Therapeutic indications:** Gliolan® is indicated in adult patients for visualisation of malignant tissue during surgery for malignant glioma (WHO grade III and IV). **Posology and method of administration:** This medicinal product should only be used by experienced neurosurgeons conversant with surgery of malignant glioma and in-depth knowledge of functional brain anatomy who have completed a training course in fluorescence-guided surgery. The recommended dose is 20 mg 5-ALA HCl per kilogram body weight. The solution should be administered orally three hours (range 2-4 hours) before anaesthesia. If the surgery is postponed by more than 12 hours, surgery should be re-scheduled for the next day or later. Another dose of this medicine can be taken 2–4 hours before anaesthesia. **Contraindications:** Hypersensitivity to the active substance or porphyrins; acute or chronic types of porphyria; pregnancy. **Undesirable effects:** Adverse reactions observed after the use for fluorescence-guided glioma resection are divided into the following two categories: Immediate reactions occurring after oral administration of the medicinal product before anaesthesia (= active substance-specific side effects); combined effects of 5-ALA, anaesthesia and tumour resection (= procedure-specific side effects). **Substance-specific side effects:** *Uncommon:* Hypotension; nausea, photosensitivity reaction, photodermatosis. **Procedure-related side effects:** The extent and frequency of procedure-related neurological side effects depend on the localisation of the brain tumour and the degree of resection of tumour tissue lying in eloquent brain areas. *Very common:* Anaemia, thrombocytopenia, leukocytosis. Blood bilirubin, alanine aminotransferase, aspartate aminotransferase, gamma glutamyltransferase or blood amylase increased. *Common:* Neurological disorders (e.g. hemiparesis, aphasia, convulsions, hemianopsia). Thromboembolism. Vomiting, nausea. *Uncommon:* Brain oedema, hypotension. *Very rare:* Hypaesthesia; diarrhoea. One case of moderate chills; one respiratory insufficiency after overdose, which resolved completely. **Legal classification**: POM (prescription only medicine). **Price per vial:** € 980/ £ 950 ex. Factory. **Marketing authorisation number:** EU/1/07/413/001-003
Marketing authorisation holder: photonamic GmbH & Co. KG, Eggerstedter Weg 12, 25421 Pinneberg, Germany. **Distribution:** medac GmbH, Theaterstraße 6; 22880 Wedel, Germany.
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Gliolan® has been authorised in all countries of the EU as well as in Iceland, Norway, United Kingdom