GB Prescribing Information - Please refer to the Summary of Product Characteristics (SmPC) before prescribing

Gliolan® (5-aminolevulinic acid) 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. See SmPC for details of other adverse events.
Legal classification: POM (prescription only medicine).
Price per vial: £950 ex. Factory.
Marketing authorisation number: PLGB 45451/0002
Marketing authorisation holder: photonamic GmbH & Co. KG, Eggerstedter Weg 12, 25421 Pinneberg, Germany.
Product information in the UK: medac Pharma, Scion House, Stirling University Innovation Park, Stirling FK9 4NF. T:01786 458086, F:01786 458032. info@medacpharma.co.uk
Date of revision of text: 11.03.2022

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to medac drug safety at: Photonamic-PhV@spm2-safety.com

NI Prescribing Information - Please refer to the Summary of Product Characteristics (SmPC) before prescribing

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Legal classification: POM (prescription only medicine).
Price per vial: £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.
Product information in the UK: medac Pharma, Scion House, Stirling University Innovation Park, Stirling FK9 4NF. T:01786 458086, F:01786 458032. info@medacpharma.co.uk
Date of revision of text: 28/04/2023

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to medac drug safety at: Photonamic-PhV@spm2-safety.com