

**Gliolan® Product Information Leaflet**  
*(aminolevulinic acid hydrochloride)*  
30 mg/mL Powder for Oral Solution

**GLIOLAN®**

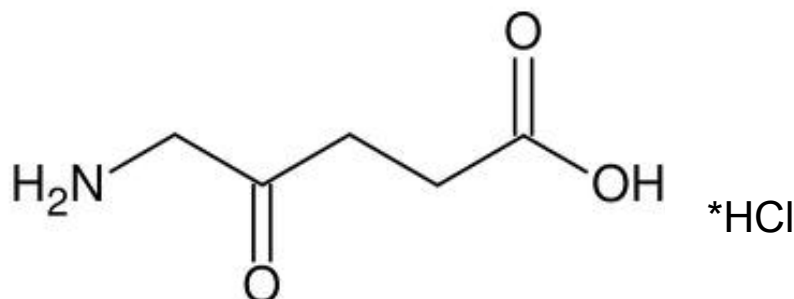
**PRODUCT INFORMATION**

**Name of Medicine**

Gliolan (aminolevulinic acid hydrochloride) 30 mg/mL powder for oral solution.

Chemical Formula:  $C_5H_9NO_3 \cdot HCl$

Chemical Structure:



CAS No: 5451-09-2

Molecular Weight: 167.59 g/mol

Freely soluble in water

pKa1: 3.90

pKa2: 8.05

pH of reconstituted solution: 2.2 – 2.8

**Description**

Gliolan is supplied in a vial as a powder for oral solution.

The powder is a white to off-white cake.

One vial contains 1.5 g of aminolevulinic acid hydrochloride (ALA HCl), equivalent to 1.17 g of aminolevulinic acid.

One mL of reconstituted solution contains 30 mg of aminolevulinic acid hydrochloride (ALA HCl), equivalent to 23.4 mg of aminolevulinic acid.

**Pharmacology**

Mechanism of action:

Aminolevulinic acid (ALA) is a natural biochemical precursor of heme that is metabolised in a series of enzymatic reactions to fluorescent porphyrins, particularly PPIX. ALA synthesis is regulated by an intracellular pool of free heme via a negative feedback mechanism.

Administration of excess exogenous ALA avoids the negative feedback control, and accumulation of PPIX occurs in target tissue. In the presence of visible light, fluorescence of

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PPIX (photodynamic effect) in certain target tissues can be used for photodynamic diagnosis.

### Pharmacodynamic effects:

Systemic administration of ALA results in an overload of the cellular porphyrin metabolism and accumulation of PPIX in various epithelia and cancer tissues. Malignant glioma tissue (WHO-grade III and IV, e.g. glioblastoma multiforme, gliosarcoma or anaplastic astrocytoma) has also been demonstrated to synthesise and accumulate porphyrins in response to ALA administration. The concentration of PPIX is significantly lower in white matter than in cortex and tumour. Tissue surrounding the tumour and normal brain may also be affected. However, ALA induced PPIX formation is significantly higher in malignant tissue than in normal brain.

In contrast, in low-grade tumours (WHO-grade I and II, e.g. medulloblastoma, oligodendroglioma) no fluorescence could be observed after application of the active substance. Brain metastases revealed inconsistent or no fluorescence.

The phenomenon of PPIX accumulation in WHO grade III and IV malignant gliomas may be explained by higher ALA uptake into the tumour tissue or an altered pattern of expression or activity of enzymes (e.g. ferrochelatase) involved in haemoglobin biosynthesis in tumour cells. Explanations for higher ALA uptake include a disrupted blood-brain barrier, increased neo-vascularisation, and the overexpression of membrane transporters in glioma tissue.

After excitation with blue light ( $\lambda=400-410$  nm), PPIX is strongly fluorescent (peak at  $\lambda=635$  nm) and can be visualised after appropriate modifications to a standard neurosurgical microscope.

Fluorescence emission can be classified as intense (solid) red fluorescence (corresponds to vital, solid tumour tissue) and vague pink fluorescence (corresponds to infiltrating tumour cells), whereas normal brain tissue lacking enhanced PPIX levels reflects the violet-blue light and appears blue.

## **Pharmacokinetic Properties**

### General characteristics

Gliolan shows good solubility in aqueous solutions. After ingestion, ALA itself is not fluorescent but is taken up by tumour tissue (*see Pharmacodynamics*) and is intracellularly metabolised to fluorescent porphyrins, predominantly PPIX.

### Absorption

ALA as drinking solution is rapidly and completely absorbed and peak plasma levels of ALA are reached 0.5–2 hours after oral administration of 20 mg/kg body weight. The median (range)  $C_{max}$  value was 20.8 (11.6 – 27.7) mg/L in normal subjects and 8.2 (7.4 – 9.7) mg/L in patients. The reason for the difference has not been established. Plasma levels return to baseline values 24 hours after administration of an oral dose of 20 mg/kg body weight. The influence of food has not been investigated because Gliolan is generally given on empty stomach prior to induction of anaesthesia.

### Distribution and biotransformation

ALA is preferentially taken up by the liver, kidney, endothelials and skin as well as by malignant gliomas (WHO grade III and IV) and metabolised to fluorescent PPIX. Four hours after oral administration of 20 mg/kg body weight ALA HCl, the maximum PPIX plasma level

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is reached. PPIX plasma levels rapidly decline during the subsequent 20 hours and are not detectable anymore 48 hours after administration. At the recommended oral dose of 20 mg/kg body weight, tumour to normal brain fluorescence ratios are usually high and offer lucid contrast for visual perception of tumour tissue under violet-blue light for at least 9 hours.

Besides tumour tissue, faint fluorescence of the choroid plexus was reported. ALA is also taken up and metabolised to PPIX by other tissues, e.g. liver, kidneys or skin (see *Precautions*). Plasma protein binding of ALA is unknown.

### Elimination

ALA is eliminated quickly with a terminal half-life of 1-3 hours. The shorter half-life was seen in normal subjects and the longer half-life in patients. Approximately 30% of an orally administered dose of 20 mg/kg body weight is excreted unchanged in urine within 12 hours.

### Linearity/non-linearity

By regression analysis, the  $AUC_{0-inf}$  of ALA plasma levels versus dose was linear over the dose range (0.2, 2, and 20 mg/kg) studied ( $R^2 = 0.9998$ ). Dose proportionality was not found for the active metabolite, PPIX, within 12 hours in normal patients.

### Renal or hepatic impairment

Pharmacokinetics of ALA in patients with renal or liver impairment has not been investigated.

## **Clinical Trials**

In a phase I/II trial including 21 patients, a dose-efficacy relationship between the dose levels and the extent and quality of fluorescence in the tumour core was detected: higher doses of ALA enhanced the fluorescence quality and the fluorescence extent of the tumour core compared to demarcation of the tumour core under standard white illumination in a monotone, non-falling fashion. The highest dose (20 mg/kg body weight) was determined to be the most efficient.

A positive predictive value of tissue fluorescence of 84.8 % (90 % CI: 70.7 %-93.8 %) was found. This value was defined as the percentage of patients with positive tumour cell identification in all biopsies taken from areas of weak and strong fluorescence. The positive predictive value of strong fluorescence was higher (100.0 %; 90 % CI: 91.1 %-100.0 %) than of weak fluorescence (83.3 %; 90 % CI: 68.1 %-93.2 %). Results were based on a phase II trial including 33 patients receiving ALA HCl in a dose of 20 mg/kg body weight.

The resulting fluorescence was used as an intraoperative marker for malignant glioma tissue with the aim of improving the surgical resection of these tumours.

In a phase III trial with 349 patients with suspected malignant glioma amenable to complete resection of contrast-enhancing tumour were randomised to fluorescence-guided resection after administration of 20 mg/kg body weight ALA HCl or conventional resection under white light. Contrast-enhancing tumour was resected in 64 % of patients in the experimental group compared to 38 % in the control-group ( $p < 0.001$ ).

At the visit six months after tumour resection, 20.5 % of ALA treated-patients and 11 % of patients who underwent standard surgery were alive at the six-month visit without progression. The difference was statistically significant using the chi-square test ( $p = 0.015$ ). No significant increase in overall survival has been observed in this trial, however, it was not powered to detect such a difference.

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## **Preclinical Safety Data**

Standard safety pharmacology experiments were performed under light protection in the mouse, rat and dog. ALA administration does not influence the function of the gastrointestinal and central nervous system. A slight increase in saluresis cannot be excluded.

Single administration of high doses of ALA to mice or rats leads to unspecific findings of intolerance without macroscopic abnormalities or signs of delayed toxicity. Repeat-dose toxicity studies performed in rats and dogs demonstrate dose-dependent adverse reactions affecting changes in bile duct histology (non-reversible within a 14 day recovery period), transient increase in transaminases, LDH, total bilirubin, total cholesterol, creatinine, urea and vomiting (only in dogs). Signs of systemic toxicity (cardiovascular and respiratory parameters) occurred at higher doses in the anaesthetised dog: at 45 mg/kg body weight intravenously a slight decrease in peripheral arterial blood pressure and systolic left ventricular pressure was recorded. Five minutes after administration, the baseline values had been reached again. The cardiovascular effects seen are considered to be related to the intravenous route of administration.

Phototoxicity observed after ALA treatment *in vitro* and *in vivo* is obviously closely related to dose- and time- dependent induction of PPIX synthesis in the irradiated cells or tissues. Destruction of sebaceous cells, focal epidermal necrosis with a transient acute inflammation and diffuse reactive changes in the keratinocytes as well as transient secondary oedema and inflammation of dermis are observed. Light exposed skin recovered completely except for a persistent reduction in the number of hair follicles. Accordingly, general light protective measures of eyes and skin are recommended for at least 24 hours after administration of Gliolan.

Although pivotal studies on the reproductive and developmental behaviour of ALA have not been performed, it can be concluded that ALA induced porphyrin synthesis may lead to embryotoxic activity in mouse, rat and chick embryos only under the condition of direct concomitant light exposure. Gliolan should, therefore, not be administered to pregnant women. Excessive single dose treatment of rats with ALA reversibly impaired male fertility for two weeks after dosing.

The majority of genotoxicity studies performed in the dark do not reveal a genotoxic potential of ALA. The compound potentially induces photogenotoxicity after subsequent irradiation or light exposure, which is obviously related to the induction of porphyrin synthesis. Long-term *in vivo* carcinogenicity studies have not been conducted. However, considering the therapeutic indication, a single oral treatment with ALA might not be related to any serious potential carcinogenic risk.

## **Indications**

Gliolan is indicated in adult patients for visualisation of malignant tissue during surgery for malignant gliomas that are glioblastoma multiforme (GBM) on preoperative imaging, and who are intended for resection of the tumour.

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### **Contraindications**

- Hypersensitivity to ALA or porphyrins.
- Acute or chronic types of porphyria.
- Pregnancy (see *Precautions; Use in Pregnancy and Preclinical safety data*)

### **Precautions**

Gliolan should only be used by experienced neurosurgeons conversant with surgery of malignant gliomas and in-depth knowledge of functional brain anatomy who have completed a training course in fluorescence-guided surgery.

ALA-induced fluorescence of brain tissue does not provide information about the tissue's underlying neurological function. Therefore, resection of fluorescing tissue should be weighed up carefully against the neurological function of fluorescing tissue.

Special care must be taken in patients with a tumour in the immediate vicinity of an important neurological function and pre-existing focal deficits (e.g. aphasia, vision disturbances and paresis etc.) that do not improve on corticosteroid treatment. Fluorescence-guided resection in these patients has been found to impose a higher risk of critical neurological deficits. A safe distance to eloquent cortical areas and subcortical structures of at least 1 cm should be maintained independent of the degree of fluorescence.

In all patients with a tumour in the vicinity of an important neurological function, either pre- or intraoperative measures should be used to localise that function relative to the tumour in order to maintain safety distances.

After administration of Gliolan, exposure of eyes and skin to strong light sources (e.g. operating illumination, direct sunlight or brightly focused indoor light) should be avoided for 24 hours.

Co-administration with other potentially phototoxic substances (e.g. tetracyclines, sulfonamides, fluoroquinolones, hypericin extracts) should be avoided (see *Preclinical safety data*).

Within 24 hours after administration, other potentially hepatotoxic medicinal products should be avoided.

In patients with pre-existing cardiovascular disease, Gliolan should be used with caution since literature reports have shown decreased systolic and diastolic blood pressures, pulmonary artery systolic and diastolic pressure as well as pulmonary vascular resistance.

### **Patients with Renal or Hepatic Impairment**

No trials have been performed in patients with clinically relevant hepatic or renal impairment. Therefore, Gliolan should be used with caution in such patients.

### **Effects on Fertility**

There are no data available regarding the influence of Gliolan on fertility.

### **Use in Pregnancy (Category C)**

There are no or limited amount of data from the use of Gliolan in pregnant woman. Some limited animal studies suggest an embryotoxic activity of ALA plus light exposure (see *Preclinical safety data*). Therefore, Gliolan should not be used during pregnancy.

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### **Use in Lactation**

It is unknown whether ALA or its metabolite protoporphyrin IX (PPIX) is excreted in human breast milk. The excretion of ALA or PPIX in milk has not been studied in animals. Breast-feeding should be interrupted for 24 hours after treatment with Gliolan.

### **Use In Children**

The safety and efficacy of ALA in children and adolescents aged 0 to 18 has not yet been established. No data are available.

### **Use In the Elderly**

There are no special instructions for use in elderly patients with regular organ function.

### **Interactions with Other Medicines**

Patients should not be exposed to any photosensitizing agent up to 2 weeks after administration of Gliolan.

In the absence of compatibility studies, Gliolan must not be mixed with other medicinal products.

### **Effects on Ability to Drive and Use Machines**

Not relevant, as the surgical procedure itself will have an influence on the ability to drive and use machines.

### **Adverse Effects**

#### Summary of the safety profile:

Adverse reactions observed after the use of Gliolan 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 ALA, anaesthesia, and tumour resection (= procedure-specific side effects).

Side effects of concern were photosensitivity as drug-related effect; neurological disorders (e.g. convulsions, hemiparesis, and aphasia); pulmonary embolism that were more frequent in patients receiving ALA and surgery; and anaemia, thrombocytopenia and leukocytosis seen with equal frequency after surgery, with and without ALA. Further frequently observed side effects are vomiting, nausea and increase of blood bilirubin, alanine aminotransferase, aspartate aminotransferase, gamma glutamyltransferase and blood amylase.

#### Tabulated summary of adverse reactions

Very common ( $\geq 1/10$ )

Common ( $\geq 1/100$  to  $< 1/10$ )

Uncommon ( $\geq 1/1,000$  to  $< 1/100$ )

Rare ( $\geq 1/10,000$  to  $< 1/1,000$ )

Very rare ( $< 1/10,000$ )

Not known (cannot be estimated from the available data).

#### **Substance-specific side effects:**

Cardiac disorders	Uncommon: hypotension
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Gastrointestinal disorders	<u>Uncommon:</u> nausea
Skin and subcutaneous tissue disorders	<u>Uncommon:</u> photosensitivity reaction, photodermatitis

**Procedure-related Side Effects:**

The extent and frequency of procedure-related neurological side effects depends on the localisation of the brain tumour and the degree of resection of tumour tissue lying in eloquent brain areas (see *Precautions* ).

Blood and lymphatic system disorders	<u>Very common:</u> anaemia, thrombocytopenia, leukocytosis
Nervous system disorders	<u>Common:</u> neurological disorders (e.g. hemiparesis, aphasia, convulsions, hemianopsia) <u>Very rare:</u> hypoesthesia
Cardiac disorders	<u>Uncommon:</u> hypotension
Vascular disorders	<u>Common:</u> thromboembolism
Gastrointestinal disorders	<u>Common:</u> vomiting, nausea <u>Very rare:</u> diarrhoea
Hepatobiliary disorders	<u>Very common:</u> blood bilirubin increased, alanine aminotransferase increased, aspartate aminotransferase increased, gamma glutamyltransferase increased, blood amylase increased

Description of selected adverse reactions:

In a single-arm trial including 21 healthy male volunteers, erythema of the skin could be provoked by direct exposure to UVA light up to 24 hours after oral application of 20 mg/kg body weight ALA HCl. An adverse drug reaction of mild nausea was reported in 1 out of 21 volunteers.

In another single-centre trial, 21 patients with malignant glioma received 0.2, 2, or 20 mg/kg body weight ALA HCl followed by fluorescence-guided tumour resection. The only adverse reaction reported in this trial was one case of mild sunburn occurring in a patient treated with the highest dose.

In a single-arm trial including 36 patients with malignant glioma, drug reactions were reported in four patients (one patient: mild diarrhoea in one patient: moderate hypesthesia in another patient: moderate chills in another patient, and arterial hypotension 30 minutes after application of ALA in another patient). All patients received the medicinal product in a dose of 20 mg/kg body weight and underwent fluorescence-guided resection. Follow-up time was 28 days.

In a comparative, unblinded phase III trial (MC-ALS.3/GLI), 201 patients with malignant gliomas received ALA HCl in a dose of 20 mg/kg body weight and 176 of these patients

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underwent fluorescence-guided resection with subsequent radiotherapy. 173 patients received standard resection without administration of the medicinal product and subsequent radiotherapy. Follow-up time comprised at least 180 days after administration. At least possibly related adverse reactions were reported in 2/201 (1.0 %) patients: mild vomiting 48 hours after trial surgery, and mild photosensitivity 48 hours after study surgery. In patients undergoing fluorescence-guided resection, the incidence of pulmonary embolism was significantly increased (7.4% cf 1.2%, p=0.006). However, the median time of onset of pulmonary embolism after study surgery was 35 days (range 1-150 days). Another patient accidentally received an overdose of the medicinal product (3000 mg instead of 1580 mg). Respiratory insufficiency, which was reported in this patient, was managed by adaptation of ventilation and resolved completely. A more pronounced transient increase of liver enzymes without clinical symptoms was observed in the ALA treated patients. Peak values occurred between 7 and 14 days after administration. Increased levels of amylase, total bilirubin, and leukocytes, but decreased levels of thrombocytes and erythrocytes were observed, however differences between treatment groups were not statistically significant.

The following table shows adverse events reported with a frequency of > 1% of patients in this trial.

*Frequency distribution of adverse events reported with a frequency of > 1% in trial MC-ASP.3/GLI excluding serious adverse events (n [%])*

<b>Adverse event</b>	<b>ALA group</b>	<b>Control group</b>	<b>P value</b>
Number of patients	176 (100%)	173 (100%)	
Any adverse event	109 (61.9%)	100 (57.8%)	0.431
Nausea	6 (3.4%)	8 (4.6%)	0.597
Vomiting	2 (1.1%)	5 (2.9%)	0.281
Hypertension	3 (1.7%)	0 (0.0%)	0.248
Thrombophlebitis	5 (2.8%)	6 (3.5%)	0.769
Cough	3 (1.7%)	0 (0.0%)	0.248
Neuro-sensory	6 (3.4%)	3 (1.7%)	0.502
Neuro-motor	25 (14.2%)	20 (11.6%)	0.524
Facial palsy	6 (3.4%)	7 (4.0%)	0.785
Neuro-cortical	11 (6.3%)	7 (4.0%)	0.469
Neuro-mood	3 (1.7%)	5 (2.9%)	0.500
Neuro-headache	13 (7.4%)	13 (7.5%)	1.000
Personality change	16 (9.1%)	9 (5.2%)	0.213
Dizziness / Vertigo	7 (4.0%)	6 (3.5%)	1.000
Speech impairment	26 (14.8%)	23 (13.3%)	0.759
Seizures	9 (5.1%)	10 (5.8%)	0.818
Ataxia	13 (7.4%)	6 (3.5%)	0.156
Hearing disorders	5 (2.8%)	2 (1.2%)	0.448
Blurred vision	26 (14.8%)	13 (7.5%)	0.041
Alopecia	3 (1.7%)	1 (0.6%)	0.623
Fever	8 (4.5%)	3 (1.7%)	0.219
Infection	7 (4.0%)	8 (4.6%)	0.798
Pain	2 (1.1%)	6 (3.5%)	0.172
Fatigue	3 (1.7%)	4 (2.3%)	0.722



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The following table shows serious adverse events reported with a frequency of > 1% of patients observed in this trial up until 180 days after study surgery

*Frequency distribution of all SAEs reported up until 180 days after study surgery (n [%])*

Serious adverse event	ALA group	Control group	P value
Number of patients	176 (100%)	173 (100%)	
Any SAE	54 (30.7%)	40 (23.1%)	0.118
Condition aggravated	3 (1.7%)	2 (1.2%)	1.000
Aphasia	6 (3.4%)	1 (0.6%)	0.121
Convulsions (other than grand mal)	12 (6.8%)	5 (2.9%)	0.134
Convulsions Grand Mal	7 (4.0%)	5 (2.9%)	0.771
Hemiparesis	8 (4.5%)	4 (2.3%)	0.379
Arrhythmia	2 (1.1%)	1 (0.6%)	1.000
Embolism pulmonary	13 (7.4%)	2 (1.2%)	0.006
Thrombosis	3 (1.7%)	3 (1.7%)	1.000
Psychosis	3 (1.7%)	1 (0.6%)	0.623

The following table shows the percentage of patients with laboratory parameters out of normal range observed in trial MC-ASP.3/GLI.

*Percentage of patients with laboratory parameters above upper limit of normal*

Control date	Baseline		24 hours		7 days		6 weeks	
	ALA	Control	ALA	Control	ALA	Control	ALA	Control
Treatment	ALA	Control	ALA	Control	ALA	Control	ALA	Control
ALT	25.4	36.4	50.2	28.3	64.8	63.7	25.8	21.7
AST	6.5	5.8	33.8	8.1	23.1	14.0	7.2	6.0
g-GT	31.8	26.0	41.8	24.9	65.3	56.1	35.6	29.5
Total bilirubin	6.5	9.2	18.4	11.6	2.5	2.9	2.6	1.2
Creatinine	11.4	6.4	1.5	1.7	3.5	2.3	3.6	6.0
Amylase	8.0	12.1	34.3	28.9	14.6	18.7	6.7	6.6
Leukocytes	62.2	63.0	85.6	88.4	72.4	66.1	19.1	21.7

*Percentage of patients with laboratory parameters below lower limit of normal*

Control date	Baseline		24 hours		7 days		6 weeks	
	ALA	Control	ALA	Control	ALA	Control	ALA	Control
Treatment	ALA	Control	ALA	Control	ALA	Control	ALA	Control
Haematocrit	9.5	7.5	64.2	59.5	41.2	46.2	28.4	28.3
Haemoglobin	7.0	11.0	63.2	57.8	40.7	46.2	30.9	33.7
Erythrocytes	10.0	12.1	66.2	60.1	46.7	48.0	32.0	33.7
Thrombocytes	2.0	2.3	12.9	9.2	4.0	6.4	5.2	4.8

## Dosage and Administration

Gliolan should only be used by experienced neurosurgeons conversant with surgery of malignant gliomas and in-depth knowledge of functional brain anatomy who have completed a training course in fluorescence-guided surgery.

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The recommended dose is 20 mg aminolevulinic acid hydrochloride per kilogram body weight. The solution should be administered orally three hours (range 2-4 hours) before anaesthesia. Use of ALA under conditions other than the ones used in the clinical trials entail an undetermined risk.

In the absence of compatibility studies, Gliolan must not be mixed with other medicinal products.

### Reconstitution:

The oral solution is prepared by dissolving the amount of powder of one vial in 50 mL of drinking water. The reconstituted solution is a clear and colourless to slightly yellowish fluid.

Any unused product or waste material should be disposed of in accordance with local requirements.

Gliolan is for single use only and any content remaining after first use must be discarded.

### **Overdosage**

Within a clinical trial, a 63-year old patient with known cardiovascular disease was accidentally given an overdose of ALA HCl (3000 mg instead of 1580 mg). During surgery he developed respiratory insufficiency, which was managed by adaptation of ventilation. After surgery the patient also displayed facial erythema. It was stated that the patient had been exposed to more light than permitted for the trial. Respiratory insufficiency and erythema completely resolved.

In the event of overdose, supportive measures should be provided as necessary, including sufficient protection from strong light sources (e.g. direct sunlight).

For information on the management of overdosage, contact the Poisons Information Centre on 131 126 (Australia) and 0800 764 766 (New Zealand).

### **Presentation and Storage Conditions**

Gliolan is supplied as white to off white powder in a glass vial.

One vial contains 1.17 g of aminolevulinic acid, corresponding to 1.5 g aminolevulinic acid hydrochloride.

One mL of reconstituted solution contains 23.4 mg of aminolevulinic acid, corresponding to 30 mg aminolevulinic acid hydrochloride.

Keep the vial in the outer carton in order to protect from light. Store below 25°C.

The reconstituted solution is physically-chemically stable for 24 hours at 25°C.

Use within 4 hours of reconstitution

Pack sizes: 1, 2 and 10 vials of powder in a carton.  
Not all pack sizes may be marketed.

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**Storage:**

Store the vials in original cartons below 25°C. Protect from light.

**Name and Address of Sponsor**

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**Poison Schedule of the Medicine**

S4

**Date of First Inclusion in the ARTG**

07 November 2013

**Date of the Most Recent Amendment**

08 January 2014