

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using GLIOLAN?

GLIOLAN contains the active ingredient aminolevulinic acid hydrochloride (ALA HCl). GLIOLAN is used for the visualisation of certain brain tumours (called glioblastoma multiforme) during tumour surgery.

For more information, see Section [1. Why am I using GLIOLAN?](#) in the full CMI.

### 2. What should I know before I use GLIOLAN?

Do not use if you have ever had an allergic reaction to aminolevulinic acid hydrochloride (ALA HCl).

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use GLIOLAN?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with GLIOLAN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use GLIOLAN?

- The usual dose is 20 mg GLIOLAN per kilogram body weight.
- GLIOLAN is given once only on the day of surgery, 2-4 hours before start of anaesthesia.

More instructions can be found in Section [4. How do I use GLIOLAN?](#) in the full CMI.

### 5. What should I know while using GLIOLAN?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• If you are about to be started on any new medicine, remind your doctor and pharmacist that you have recently taken, or due to be given GLIOLAN.</li><li>• If you are going to have surgery with GLIOLAN, tell the surgeon or anaesthetist about all other medicines you have taken at least in the 4 weeks before your surgery.</li><li>• If you are required to have any blood tests after your surgery with GLIOLAN, tell your doctor that you have taken this medicine.</li><li>• Protect your eyes and skin from strong light (for example direct sunlight or brightly focused indoor light) for 24 hours after administration of this medicine.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take GLIOLAN to treat any other complaints unless your doctor tells you to.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• This medicine is not expected to affect your ability to drive a car or operate machinery.</li></ul>

For more information, see Section [5. What should I know while using GLIOLAN?](#) in the full CMI.

### 6. Are there any side effects?

Side effects listed are due to the medicine and/or the surgery. The most common side effects include anemia, thrombocytopenia, leukocytosis, neurological disorders, blood clots that may obstruct blood vessels (thromboembolism), vomiting, nausea and increase in liver enzymes. Serious side effects can include nervous system related disorders, thromboembolism and blood clots that may move to the lungs (pulmonary embolism).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# GLIOLAN®

Active ingredient(s): aminolevulinic acid hydrochloride (ALA HCl)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using GLIOLAN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GLIOLAN.**

Where to find information in this leaflet:

1. [Why am I using GLIOLAN?](#)
2. [What should I know before I use GLIOLAN?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use GLIOLAN?](#)
5. [What should I know while using GLIOLAN?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

### 1. Why am I using GLIOLAN?

GLIOLAN contains the active ingredient aminolevulinic acid hydrochloride (ALA HCl).

GLIOLAN is used for the visualisation of certain brain tumours (called glioblastoma multiforme) during tumour surgery.

ALA HCl accumulates preferably in tumour cells where it is transformed into another similar substance. If the tumour is then exposed to blue light this new substance emits a red-violet light, which helps the surgeon to better see what is normal tissue and what is tumour tissue. This helps the surgeon to remove the tumour while sparing healthy tissue.

### 2. What should I know before I use GLIOLAN?

#### Warnings

Do not use GLIOLAN if:

- You are allergic to aminolevulinic acid hydrochloride or porphyrins (such as heme the pigment in red blood cells).
- You have, or may have, acute or chronic types of porphyria. Porphyria is a rare blood pigment disorder. This disorder can be inherited or acquired during your lifetime.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- Have any other medical conditions
- Take any medicines for any other condition

- Have heart disease. This medicine should be used with caution because the blood pressure may be decreased
- Have liver or kidney disease. This medicine should be used with caution as there is limited information on its use in patients with poor liver or kidney function
- Have or have had allergies to any other medicines, foods, preservatives or dyes
- Are a child or adolescent.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. GLIOLAN must not be used during pregnancy. It may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether this medicine enters breast milk. Breast-feeding mothers should not breast-feed for 24 hours after treatment with this medicine. Your doctor can discuss with you the risks and benefits involved.

#### GLIOLAN with food and drink

- You should not drink or eat for at least 6 hours before starting anaesthesia.
- This medicine is generally used once only, 2-4 hours before anaesthesia for surgery.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with GLIOLAN and affect how it works**, particularly medicines that may cause skin problems, such as sunburn, when the skin comes under strong light. These include:

- Some types of antibiotics such as tetracyclines, sulfonamides and fluoroquinolones
- *Hypericin extracts* used to treat mild forms of depression. One case of severe sunburn lasting for 5 days has been reported in a patient after having taken this medicine and a hypericin extract.

You should not take any such products for up to 2 weeks after you have taken GLIOLAN.

- Any medicines known to harm the liver within 24 hours of having taken GLIOLAN

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GLIOLAN.**

## 4. How do I use GLIOLAN?

This medicine is a powder that must be mixed with drinking water before use.

This will be done for you by a pharmacist or a nurse.

### How much to take

- The usual dose is 20 mg GLIOLAN per kilogram body weight. The pharmacist or nurse will calculate the exact dose you need.

### When and how to take GLIOLAN

- You have to drink the prepared solution 2-4 hours before start of anaesthesia.
- The solution has a sour taste when taken orally.
- If the anaesthesia/surgery is delayed by some hours, additional doses of this medicine must not be given.
- If the surgery is postponed by more than 12 hours, surgery should be re-scheduled for the next day or later. If the surgery is delayed by a day or more another dose of this medicine can be taken 2-4 hours before anaesthesia.

### If you forget to use GLIOLAN

GLIOLAN is given once only on the day of surgery, 2-4 hours before start of anaesthesia.

If you have forgotten to take this medicine during this time period, it is not advisable to take it just before start of anaesthesia. In this case, anaesthesia and surgery must be postponed for at least 2 hours, if possible.

### If you use too much GLIOLAN

If you have taken more GLIOLAN than you should, your doctor will decide on any necessary measures to avoid any problems, including sufficient protection from strong light (for example direct sunlight).

Symptoms of an overdose may include skin rash and problems breathing.

If you think that you have used too much GLIOLAN, you may need urgent medical attention.

#### You should immediately:

- If in Australia: phone the Poisons Information Centre (**by calling 13 11 26**)  
If in New Zealand phone the Centre for Adverse reaction monitoring (**by calling 03 479 7185**), or
- Contact your doctor, or

- Go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using GLIOLAN?

### Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you have recently taken, or due to be given GLIOLAN.
- If you are going to have surgery, tell the surgeon or anaesthetist about all other medicines you have taken at least in the 4 weeks before your surgery.
- If you are required to have any blood tests after your surgery, tell your doctor that you have taken this medicine. It may interfere with the results of some tests.

Remind any doctor, dentist or pharmacist you visit that you have recently taken, or due to be given GLIOLAN.

### Things to be careful of

#### Light exposure

- Protect your eyes and skin from strong light (for example direct sunlight or brightly focused indoor light) for 24 hours after administration of this medicine.

### Things you must not do

- Do not take GLIOLAN to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how GLIOLAN affects you.**

This medicine is not expected to affect your ability to drive a car or operate machinery.

### Looking after your medicine

GLIOLAN will be stored in the pharmacy or in the ward. The medicine is kept in its original packaging where the temperature stays below 25°C protected from light.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Some of the side effects listed are due to the medicine, anaesthesia and/or the surgery, or a combination of these.

### Less serious side effects

Less serious side effects	What to do
<p><b>General or affecting different parts of the body:</b></p> <ul style="list-style-type: none"> <li>• Skin reactions (for example rash, which may look like sunburn) caused by sunlight and/or brightly focused indoor lights.</li> <li>• Decrease in your blood pressure which you may experience as feeling weak or dizzy.</li> </ul> <p><b>Stomach and digestive system related:</b></p> <ul style="list-style-type: none"> <li>• Nausea. Symptoms may include stomach discomfort, feeling sick or the feeling that you are going to vomit.</li> <li>• Vomiting (sickness).</li> </ul> <p><b>Blood related:</b></p> <ul style="list-style-type: none"> <li>• May include mild alterations of blood cell counts (red and white cells, platelets). This will only be evident as a result of a laboratory test your doctor may order.</li> </ul> <p><b>Liver related:</b></p> <ul style="list-style-type: none"> <li>• May include increased levels of bilirubin, a bile pigment produced in the liver by breakdown of red blood cells, in the blood which might cause jaundice (a yellowing of the skin, mucous membranes and eyes)</li> <li>• May include pain in the upper right area of your abdomen, nausea, vomiting, a general sense of not feeling well, difficulty in breathing, disorientation or confusion, or sleepiness; these could be signs that indicate the inability of the liver to perform its normal function.</li> <li>• May include a slight increase in levels of liver enzymes (transaminases and gamma-glutamyl transpeptidase [GGT]) which may indicate inflammation or damage to the liver. This will</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

only be evident as a result of a laboratory test your doctor may order.

#### Pancreas related:

- May include a slight increase in levels of pancreatic enzyme (amylase) which may indicate inflammation of the pancreas. This will only be evident as a result of a laboratory test your doctor may order.

### Serious side effects

Serious side effects	What to do
<p><b>Nervous system related:</b></p> <p>Neurological disorders which may include</p> <ul style="list-style-type: none"> <li>• Partial paralysis of one side of the body (hemiparesis)</li> <li>• Total or partial loss of ability to use or understand language (aphasia)</li> <li>• Seizures (convulsions)</li> <li>• Blindness for half the field of vision in one or both eyes (hemianopsia)</li> <li>• Swelling of the brain (brain oedema). Symptoms may include one or more of the following – headache, neck pain, nausea or vomiting and dizziness</li> </ul> <p><b>Vascular related:</b></p> <ul style="list-style-type: none"> <li>• Blood clot that moves to the lungs (pulmonary embolism). Symptoms are typically sudden in onset and may include chest pain, shortness of breath or rapid breathing, cough, fast heart rate or palpitations.</li> <li>• Blood clots (thromboembolism) that may obstruct blood vessels. Symptoms may include paresthesia (abnormal nerve sensations such as pins-and-needles, tingling, burning, prickling or similar feelings), weakness and numbness.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects in Australia to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems)

If you are located in New Zealand, contact Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

Botany Town Centre  
588 Chapel Road, East Tamaki, Auckland 2013, New Zealand  
Tel: +64 9801 0299

This leaflet was prepared in November 2025.

## 7. Product details

This medicine is only available with a doctor's prescription.

### What GLIOLAN contains

<b>Active ingredient (main ingredient)</b>	Aminolevulinic acid hydrochloride
<b>Other ingredients (inactive ingredients)</b>	None

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of this ingredient.**

### What GLIOLAN looks like

GLIOLAN is a powder for oral solution. It is a white to off-white cake powder stored in a glass vial (Aust R 202549).

When the powder is dissolved in water the solution is a clear and colourless to slightly yellowish fluid.

GLIOLAN is provided in a glass vial and presented in packs of 1, 2 and 10 vials. Not all pack sizes may be marketed.

### Who distributes GLIOLAN

In Australia

Specialised Therapeutics Glio Pty Ltd  
Level 2, 17 Cotham Road  
Kew, Victoria 3101  
Ph: 1300 798 820  
[www.stbiopharma.com](http://www.stbiopharma.com)

In New Zealand:

Specialised Therapeutics Limited  
Level 1, The Lane,