

GLIOLAN®

(Gliolan or Glee-o-lan or Gl-io-lan)

Aminolevulinic acid hydrochloride (ALA HCl)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Gliolan. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Gliolan against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet

You may need to read it again.

What Gliolan is used for

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

Gliolan contains a substance called aminolevulinic acid hydrochloride (ALA HCl). 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is not addictive.

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

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

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take it

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing aminolevulinic acid hydrochloride or porphyrins (such as heme the pigment in red blood cells)

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if 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.

Do not take this medicine if you are pregnant or suspect you may be pregnant.

It may affect your developing baby if you take it during pregnancy.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Heart disease. This medicine should be used with caution because the blood pressure may be decreased.
- 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.

Tell your doctor if you are breast-feeding.

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.

If you have not told your doctor about any of the above, tell him/her before you start taking Gliolan.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Gliolan may interfere with each other 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 *tetracycline's, 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

These medicines may be affected by Gliolan or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Taking 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.

How to take it

Follow all directions given to you by your doctor or pharmacist carefully.

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.

How to take it

You have to drink the prepared solution 2-4 hours before start of anaesthesia. The solution has a sour taste when taken orally.

When to take it

You have to drink the prepared solution 2-4 hours before start of anaesthesia.

If the anaesthesia/surgery is delayed by some hours, additional doses of this medicine must not be given. If the surgery is delayed by one or more days, another dose of this medicine can be taken 2-4 hours before start of anaesthesia.

If you forget to take Gliolan

This medicine 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 take too much (overdose)

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.

While you are using it

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.

Tell any other doctors, dentists, and pharmacists who treat you that you have recently taken or are due to be treated with 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.

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.

Things to be careful of

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.

Side effects

Some of the side effects listed are due to a combination of the medicine, anaesthesia and the surgery. Other side effects may occur after having taken Gliolan and before start of anaesthesia.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea (unsettled stomach)
- vomiting (sickness)
- skin reaction, which may look like sunburn
- decrease in your blood pressure, which you experience as feeling weak or dizzy.

Tell your doctor immediately if you notice any of the following:

- neurological disorders (disorders that affect the nervous system) like:
 - hemiparesis (partial paralysis of one side of the body),
 - aphasia (total or partial loss of ability to use or understand language),
 - convulsions (seizures) and
 - hemianopsia (blindness for half the field of vision in one or both eyes);
- thromboembolism (blood clots that may obstruct blood vessels). The symptoms may include:
 - paresthesias (abnormal nerve sensations such as pins-and-needles, tingling, burning, prickling or similar feelings)
 - weakness
 - numbness;
- pulmonary embolism (a blood clot that moves to the lungs). The symptoms are typically sudden in onset and may include:
 - chest pain
 - shortness of breath or rapid breathing
 - cough
 - fast heart rate or palpitations;
- Symptoms of brain oedema (swelling of the brain) that can include one or more of the following:
 - headache
 - neck pain
 - nausea or vomiting
 - dizziness.

The following side effects can also occur however these would only be found when your doctor does tests after surgery to check your progress;

- mild alterations of blood cell counts (red and white cells, platelets)

- slight increase of some enzymes (transaminases, γ -GT, amylase), or
- bilirubin (a bile pigment produced in the liver by breakdown of red blood pigment in the blood)

These side effects are usually mild and short-lived and will completely resolve within a few weeks. Usually you would not experience any symptoms at all when these changes occur.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Product description

What it looks like

This medicine is a powder for oral solution. It is a white to off-white cake powder stored in a glass vial.

When the powder is dissolved in water the solution is 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.

Ingredients

Gliolan contains aminolevulinic acid hydrochloride as the active ingredient.

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

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

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

Sponsor

Gliolan is supplied in Australia by:
Specialised Therapeutics Glio Pty Ltd
Level 1, 711 High Street
East Kew, Victoria 3102

Ph: 1300 798 820
Fax: 1800 798 829
www.specialisedtherapeutics.com.au

Gliolan is supplied in New Zealand by:

Specialised Therapeutics Limited
109a Ti Rakau Dr.,
Pakuranga, Auckland
2010, New Zealand

Tel: +64 9801 0299
Fax: +64 9801 0118

Under licence from: photonamic GmbH & Co. KG

This leaflet was prepared in
February 2017.

30 mg/mL: AUST R number 202549