

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS

(PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Gliolan

Powder for the preparation of an oral solution

The active ingredient and its quantity in a dosage unit:

Each vial contains:

5-aminolevulinic acid hydrochloride 1.5 g

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

- Visualization of certain brain tumors (called malignant glioma) during brain surgery.

Therapeutic class: imaging agents

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (5-aminolevulinic acid hydrochloride) or to porphyrin.
- You have porphyria or are suspected to have acute or chronic porphyria (an acquired or hereditary disorder of certain enzymes in the synthesis pathway of the red pigment in the blood).
- You are pregnant or suspect you are pregnant.

Special warnings regarding the use of the medicine

- **Before treatment with Gliolan, tell the doctor if:**
 - You have a **heart disease** or have previously had a heart disease. In this case, use the medicine with caution as blood pressure may drop.
- After taking the medicine, protect the eyes and skin from exposure to strong light (such as: direct sunlight or strong lighting) for a duration of 24 hours.
- No studies have been performed in patients with impaired liver or kidney function – use this preparation cautiously in these patients.

Children and adolescents

This medicine is not intended for children and adolescents under the age of 18, as there is no experience with Gliolan in this age group.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially inform the doctor or pharmacist if you are taking or intending to take:

- Medicines or herbal medicines that can cause skin problems during exposure to light (such as antibiotics or hypericum extracts [St. John's Wort]) – do not take these products for two weeks after taking Gliolan.
- Medicines that may harm the liver can be taken 24 hours after taking Gliolan.

Use of the medicine and food

The medicine is usually administered once, mainly 2-4 hours before anesthesia for surgery of brain tumors called glioma. Do not drink or eat at least 6 hours before the anesthesia.

Pregnancy and breastfeeding

- It is unknown whether the medicine is harmful to the fetus. Do not use if you are pregnant.
- It is unknown whether the medicine passes into breast milk. You should not breastfeed for 24 hours after taking the medicine.

Driving and operating machinery

This medicine does not affect the ability to drive or operate machinery.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

20 mg for each kg of body weight. The exact dosage will be calculated by the nurse or pharmacist.

Do not exceed the recommended dose.

How to take the medicine

- The medicine contains a powder that needs to be mixed with a glass of water before use. The preparation of the medicine will always be done by a nurse or pharmacist.
- Drink the prepared solution 2-4 hours before the anesthesia.
- If the anesthesia/surgery is delayed by a few hours (up to 12 hours), **do not** give another dose of this medicine.

- If the surgery is postponed and 12 hours or more have passed since the administration of the medicine, the surgery must be rescheduled (for the next day or later). On the day of the rescheduled surgery, an additional dose of the medicine can be taken 2-4 hours before anesthesia.

If you took an overdose or a child swallowed this medicine by mistake, refer to the doctor or to a hospital emergency room immediately and take the package of the medicine with you. The doctor will decide on the necessary measures to avoid problems, including sufficient protection from strong light (such as direct sunlight).

This medicine is given once on the day of surgery, 2-4 hours before the start of anesthesia.

If you forgot to take the medicine during this time period, it is not recommended to take it immediately before the start of anesthesia. In this case, the anesthesia and surgery should be postponed by at least two hours, if possible.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Gliolan may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

The most serious side effects include mild alterations of blood count (red and white blood cells, platelets), neurological disorders (disorders that affect the nervous system such as: hemiparesis [partial paralysis of one side of the body]), and thromboembolism (a blood clot that may block blood vessels).

Additional side effects that have been frequently observed are vomiting, nausea and slight increase of certain enzymes (transaminases, gamma-glutamyl transferase, amylase) or bilirubin (a bile pigment produced in the liver by the breakdown of red blood cells) in the blood.

Tell the doctor immediately if you have any complaints.

The side effects may occur as a result of taking the medicine before anesthesia or as a result of taking the medicine along with the anesthesia and tumor removal.

After taking Gliolan and before starting anesthesia, the following side effects may occur:

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

- Nausea, drop in blood pressure, skin reactions (for example: a rash that looks like sunburn), brain edema (swelling of the brain).

In combination with anesthesia and tumor removal, additional side effects may occur:

Very common side effects – effects that occur in more than 1 user out of 10:

- Mild alteration of blood count (red and white blood cells, platelets), slight increase of certain enzymes (transaminases, gamma-glutamyl transferase, amylase) or bilirubin (a bile pigment produced in the liver by the breakdown of red blood cells) in the blood. These changes reach their peak between 7-14 days after the surgery. These changes will completely resolve within a few weeks. Usually, you will not feel any symptom when these changes occur.

Common side effects – effects that occur in 1-10 users out of 100:

- Nausea, vomiting, neurological disorders – disorders that affect the nervous system, such as: hemiparesis (partial paralysis of one side of the body), aphasia (partial or total loss of the ability to use language or understand language), spasms (fits) and hemianopia (blindness in half of the visual field in one or both eyes), thromboembolism (a blood clot that may block blood vessels).

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

- Drop in blood pressure, brain edema (swelling of the brain).

Very rare side effects – effects that occur in less than one user out of 10,000 or side effects with unknown frequency (effects whose frequency has not yet been determined):

- Hypoesthesia (reduced sense of touch), diarrhea (loose or watery stools).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting of side effects

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.it), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.it>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package/vial. The expiry date refers to the last day of that month.

Storage conditions:

- Store at a temperature not exceeding 25°C. Store the vial in the outer package in order to protect from light.

- Store the prepared solution at 25°C and use within 24 hours of preparation.
- Do not discard medicines via waste water or the trash. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional information

What does the medicine look like and what are the contents of the package?

This medicine is a powder for oral use. The color of the powder is white to cream (off-white).

After preparation, the solution is clear and colorless to slightly yellowish in color.

Gliolan packages contain 1, 2 or 10 vials.

Not all package sizes may be marketed.

Marketing authorization holder and address: Tzamal Bio-Pharma Ltd.,

20 Hamagshimim St., Kiryat Matalon, Petach Tikva.

Name and address of the manufacturer: photonamic GmbH & Co. KG, Eggerstedter Weg

12, Pinneberg, Germany

Registration number of the medicine in the national drug registry of the Ministry of

Health: 150-85-33857.

The leaflet was revised in October 2023 in accordance with the Ministry of Health guidelines.

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