WILL GLEOLAN (aminolevulinic acid HCl) AFFECT TREATMENT THAT I RECEIVE AFTER SURGERY?

Use of Gleolan does not affect the use of other treatments for your cancer such as radiotherapy or chemotherapy.

DOES GLEOLAN TREAT THE CANCER?

Gleolan is not a treatment for cancer. Its use, as approved by the FDA, is to assist the neurosurgeon during surgery to see the brain tumor to enable safe removal of as much of it as possible.

Reference
1. Data on file, NX Development Corp.

NX Development Corp.
870 Corporate Dr #403, Lexington, KY 40503
MTF-0054

Please see the enclosed full Prescribing Information. Learn more at gleolan.com.

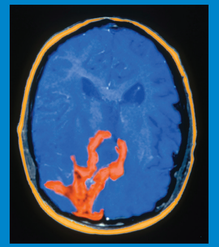
Gleolan™
(aminolevulinic acid HCl)

LEARNING MORE ABOUT GLEOLAN™ (aminolevulinic acid HCl)

Gleolan is known as an 'imaging agent' that is taken by patients before surgery to help neurosurgeons to see certain brain tumors, known as 'high-grade gliomas'

Please see the enclosed full Prescribing Information. Learn more at gleolan.com.

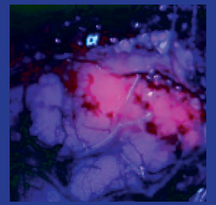
REMOVING THE TUMOR DURING SURGERY



As part of your treatment plan, your neurosurgeon will be performing surgery to remove as much of your tumor as they can safely remove. This is known as 'resection.' The amount of tumor that can be removed is determined by the tumor's size and location. The goal is to remove as much of the tumor as possible without harming areas of the brain that control critical functions such as speech or balance. Gliomas generally have very small cells that grow into brain tissue, which may make it difficult to see and resect (see image on left).

Image credit: Gregory G. Dimijian, MD/Science Source

USING GLEOLAN (aminolevulinic acid HCl) IN NEUROSURGERY



Neurosurgeons have several tools that are helpful for locating the tumor during surgery; these tools provide information that allows for removal of as much tumor tissue as possible. For your surgery, your neurosurgeon may use Gleolan. Gleolan is an oral solution, which you will drink 3 hours (between 2 to 4 hours) before you receive anesthesia for your surgery. It contains aminolevulinic acid hydrochloride (ALA HCl). During the surgery, your neurosurgeon will view the brain through special blue light filters on the surgical microscope. Under this blue light, Gleolan helps the tumor 'fluoresce' or glow a red-violet color, as shown in the image on the left. Because non-cancerous brain cells should not glow when using the blue light filters, the neurosurgeon may be able to better distinguish the tumor from normal tissue (see sample image on left). This may allow the neurosurgeon to remove more of the tumor tissue.

Each situation is different. This brochure is intended to answer some common questions about Gleolan. It does not contain all the available information, so let your doctor know of any questions or concerns you may have.

COMMON QUESTIONS AND IMPORTANT INFORMATION ABOUT GLEOLAN (aminolevulinic acid HCl)

WHAT IS GLEOLAN FOR?

Gleolan is known as an 'imaging agent' that is taken by patients before surgery to help neurosurgeons to see certain brain tumors, known as 'high-grade gliomas'.

IS THERE ANYONE WHO SHOULD NOT TAKE GLEOLAN?

You should not take Gleolan if you have an allergy to any medicine containing aminolevulinic acid or porphyrins or have a condition called porphyria.

Tell your doctor about any allergies or conditions that you have and mention all medications that you are currently taking. If you are pregnant, breastfeeding, or suspect that you may be pregnant, let your doctor know. Your doctor can discuss with you the risks and benefits involved.

IMPORTANT INFORMATION ABOUT USING GLEOLAN

Gleolan can cause a sunburn-type skin reaction, also referred to as photosensitivity. Do not take any drugs that may worsen this (such as St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulphonamides, quinolones, and tetracyclines) and do not put anything on your skin that contains aminolevulinic acid (ALA) for 24 hours before and for 24 hours after receiving Gleolan.

Errors may occur with the use of Gleolan to see tumors. Sometimes brain tumor cells may fluoresce even if they are not cancerous or those that are cancerous may not fluoresce. Also, cancer cells from other tumors or areas of swelling may fluoresce.

Serious allergic reactions to Gleolan have occurred. Your medical team should monitor you for this and should have emergency equipment ready to manage any such reaction if it occurs.

TAKING GLEOLAN (aminolevulinic acid HCl)

Your doctor and the team in the hospital will determine how much Gleolan you should take, based on your body weight, and will prepare a Gleolan solution for you to drink 3 hours (between 2 to 4 hours) before you receive anesthesia. Be sure to carefully follow all directions given to you by your doctor and nursing team. The liquid is clear/yellowish and has a sour taste.

60,000+ patients

WHEN WAS GLEOLAN APPROVED?

Gleolan was approved in the United States by the Food and Drug Administration (FDA) in 2017. In other countries, it was approved as early as 2007. To date, more than 60,000 patients have received this drug worldwide.[1]

IS GLEOLAN COVERED BY INSURANCE?

Gleolan is considered part of the surgical procedure and is covered through payment to the hospital. Contact your healthcare insurer with questions regarding coverage of Gleolan.

DIM

WHAT IS PHOTOSENSITIVITY?

Gleolan makes you more sensitive to sunlight and direct indoor lighting, referred to as photosensitivity, and can cause a sunburn-type reaction. The hospital team will make sure you are kept in low light conditions from the time you take Gleolan until you are discharged. You should maintain these low light conditions at home and avoid sunlight, until 48 hours from the time you took Gleolan. You may wish to bring a hat, sunglasses, and clothing to the hospital so that your body can be completely covered when you are discharged.

You will also need to avoid certain drugs that may worsen a potential sunburn-type reaction (such as St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulphonamides, quinolones, and tetracyclines) and do not put anything on your skin that contains ALA for 24 hours before and for 24 hours after taking Gleolan. Ask your medical team if you have any questions about this.

ARE THERE SIDE EFFECTS TO TAKING GLEOLAN (aminolevulinic acid HCl)?

Even though the active chemical in Gleolan is already in your body, you may experience some side effects from Gleolan. Tell your doctor if you experience any unusual symptoms or reactions.

The type of reactions that occurred in some patients in the week after surgery were fever (pyrexia), decrease in blood pressure (hypotension), nausea and vomiting.

Disorders that affect the nervous system happened in a small percentage of patients in the first weeks after surgery. These included: a total or partial loss of ability to use or understand language (aphasia), partial paralysis of one side of the body (hemiparesis), blindness for half the field of vision in one or both eyes (hemianopsia), headache, seizure, paralysis of one side of the body (hemiplegia), paralysis of a single limb (monoparesis), and reduced sense of touch (hypoesthesia). Swelling of the brain (brain edema) occurred in a small percentage of patients in the first 6 weeks after surgery. Neurologic events related to the surgical procedure occurred in 29% of patients and included headache, seizure, moderate loss of sensory and motor function and swelling of the brain (brain edema). The changes in neurological function returned to the same as the non-treated group during the weeks after surgery.

Inflammation or damage to your liver is possible within the first week after surgery (and may continue beyond 6 weeks). This should be monitored carefully by your doctor.

If you experience any side effects, seek immediate medical attention and tell your medical team.

You are encouraged to report any side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see the enclosed full Prescribing Information. Learn more at gleolan.com.