GLEOLAN™ PATIENT CARE CHECKLIST

Gleolan™ (aminolevulinic acid HCl)

Gleolan is an optical imaging agent indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery.

The following checklist is a guide intended to assist you in the care of your patients pre- and post-surgery. This checklist does not replace surgical protocols. **Please see the Important Safety Information on the reverse side, as well as the full Prescribing Information for Gleolan.**

1 PRIOR TO PATIENT ARRIVAL FOR SURGERY

- ☐ Remind patient of scheduled arrival time at hospital. Patient must receive Gleolan 3 hours (range 2 to 4 hours) in advance of induction of anesthesia.
- ☐ Advise patient not to take any phototoxic drugs 24 hours prior to administration such as St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulphonamides, quinolones and tetracyclines, and topical preparations containing aminolevulinic acid (ALA).
- ☐ Check patient's weight, and advise pharmacy for calculation of volumetric dose.
- ☐ Ensure that the reconstituted Gleolan from the pharmacy is stored at room temperature. Do not refrigerate.
- ☐ Due to the risk of phototoxic reactions, reduce exposure to sunlight or room lights for 48 hours after administration of Gleolan. You may wish to consider securing a room with reduced light for use after Gleolan administration.

2 GLEOLAN ADMINISTRATION: 3 HOURS (RANGE 2 TO 4 HOURS) PRIOR TO INDUCTION OF ANESTHESIA

- ☐ You may store reconstituted solution for up to 24 hours at room temperature. Do not refrigerate.
- ☐ Advise staff/anesthesiology that, as an exception to NPO status, the patient may have the appropriate weight-adjusted dose prior to anesthesia.
- ☐ Administer orally 3 hours (range 2 to 4 hours) prior to induction of anesthesia.
- ☐ Ensure that patient drinks the entire amount, as prepared in the pharmacy based on patient weight.
- ☐ Place Gleolan wristband on patient, and mark timing of administration and end of light precautions (48 hours later).
- ☐ Place the patient in an area with reduced exposure to sunlight or room lights until surgery.
- ☐ Ensure that the patient is covered sufficiently if he/she leaves the light-protected area for any reason.
- ☐ Monitor for adverse events as well as hypersensitivity reactions. See Important Safety Information on the reverse side.
- ☐ Do not exceed 20 mg/kg dosing in preparation for each surgical case; consequences of repeat dosing of Gleolan have not been studied.

3 SURGICAL PROCEDURE (MAINTAIN LOW-LIGHT PRECAUTIONS UNTIL PATIENT IS FULLY DRAPED)

4 AFTER GLEOLAN ADMINISTRATION: POSTOPERATIVE CARE

- ☐ Advise full team of photosensitivity precautions and note in patient chart.
- ☐ Place Gleolan doorhanger/window post on patient's room, and mark timing of administration and end of light precautions (48 hours later).
- ☐ Maintain reduced exposure to sunlight and room lights for 48 hours after administration.
- ☐ Drape patient to maintain reduced light precautions for transfer within the hospital (e.g. transfer to recovery, for imaging, etc.).
- ☐ Do not administer phototoxic drugs such as St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulphonamides, quinolones and tetracyclines, and topical preparations containing ALA for 24 hours post-administration.
- ☐ Advise patient to maintain reduced exposure to sunlight or room lights for 48 hours after administration of Gleolan due to risk of phototoxic reaction.
- ☐ Advise patient that it is possible to experience elevated liver enzymes (ALT and GGT) within the first week after surgery. This elevation may persist beyond 6 weeks.

QUESTIONS OR CONCERNS? CALL NX DEVELOPMENT CORP. AT 1-833-GLEOLAN (1-833-453-6526)

Please see full Prescribing Information

IMPORTANT SAFETY INFORMATION

Gleolan™
(aminolevulinic acid HCl)

CONTRAINDICATIONS

- Do not use Gleolan in patients with hypersensitivity to aminolevulinic acid (ALA) or porphyrins, or acute or chronic types of porphyria

WARNINGS AND PRECAUTIONS

- Due to the risk of phototoxic reactions, do not administer phototoxic drugs and topical preparations containing ALA for 24 hours during the perioperative period. Reduce exposure to sunlight or room lights for 48 hours after administration of Gleolan.
- Errors may occur with the use of Gleolan for intraoperative visualization of malignant glioma, including false negatives and false positives. Non-fluorescing tissue in the surgical field does not rule out the presence of tumor in patients with glioma. Fluorescence may be seen in areas of inflammation or metastases from other tumor types.
- Hypersensitivity reactions, including serious hypersensitivity reactions have occurred; these reactions include anaphylactic shock, swelling, and urticaria. Always have cardiopulmonary resuscitation personnel and equipment readily available and monitor all patients for hypersensitivity reactions.

ADVERSE REACTIONS

- Adverse reactions occurring in >1% of patients in the week following surgery were pyrexia, hypotension, nausea, and vomiting.
- Nervous system disorders occurred in 29% of patients within the first week after surgery and events occurring in >1% of patients included: aphasia (8%), hemiparesis (7.8%), hemianopsia (3.2%), headache (2.7%), seizure (1.9%), hemiplegia (1.9%), monoparesis (1.3%) and hypoesthesia (1.1%). Brain edema occurred in <1% of patients in the first 6 weeks after surgery. In a randomized clinical trial, the numbers of serious neurologic adverse events in the post operative period were higher in patients randomized to ALA fluorescence arm compared to the control arm. An imbalance was notable for the adverse events aphasia, ataxia, convulsion and hemianopsia and is likely related to the higher amount of brain resection performed in the ALA arm. At longer follow up periods, the numbers between the two arms appeared similar.
- Worsening of ≥2 Common Toxicity Criteria grades in alanine aminotransferase and gamma-glutamyl transferase occurred in 15.8% and 11.6% of patients, respectively, within the first week after surgery. Absolute levels ranged from 2 times to greater than 10 times the upper limit of normal for each parameter. At 6 weeks, these measurements remained elevated in 2.9% and 7.5% of patients, respectively. There were no cases of liver failure.

DRUG-DRUG INTERACTIONS

- See information under Warnings and Precautions regarding phototoxic reactions.

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