GLiSten The Leeds Teaching Hospitals NHS NHS Trust

Clinical Trial Prescription

Patient Name			
Date of Birth		**Consultant**	
Hospital No		**Ward**	
Trial ID number	**Assigned retrospectively**	**Cohort**	
Allergies			

Original: retain in the pharmacy site file **Copy: return to ward with 5-ALA**

5-aminolevulinic acid (5-ALA) powder for oral solution

Please also prescribe the dose on the patient's drug chart			
Date Requested	/ /	**Date Required**	/ /
Patient weight	(kg)	**Time surgery scheduled for**	:
Dose level required: (please circle)	**10mg/kg**	**20mg/kg**	**30mg/kg**
Dose	(mg)	**Rounded to (if applicable)**	(mg)
Prescribed by:		**Date**	

For Pharmacy Use Only			
Prescription Validated By		**Date**	
Quantity dispensed (number of vials)		**Batch number**	
Dispensed by (sign and print)		**Date**	
Checked by (sign and print)		**Date**	

GLiSten 5-ALA guidance leaflet issued (please tick): ☐

Administration			
Please refer to the GLiSten Trial protocol before giving this medicine ***I confirm I have read and understand the GLiSten 5-ALA information leaflet prior to administration:***			
Ward		**Nurse Signature (1)**	
Date of administration	/ /	**Nurse Signature (2)**	
Time of administration	:		
Give the calculated amount of 5-ALA in tap water at 30mg/ml between 4-6 hours before the scheduled beginning of anaesthesia			

5-ALA in Bowel Cancer Surgery

GUIDANCE FOR 5-ALA RECONSTITUTION ON THE WARD

One vial contains 1.5 g 5-aminolevulinic acid hydrochloride (5-ALA HCl). The powder is a white to off white cake.

The solution should be administered **orally** 4-6hrs prior to surgery.

The reconstituted solution is a clear and colourless to slightly yellowish fluid.

Gliolan is for single use only and any content remaining after first use must be discarded.

Reconstituted solution The reconstituted solution is physically-chemically stable for 24 hours at 25°C.

To calculate the dose of 5-ALA

1. **Find which dose cohort the patient is in from the patient case notes**
2. **Weigh the patient – in kg**
3. **Calculate the total dose in mg**

- Patients weight in kg X 20 (If in 20mg/kg cohort) = total dose in mg required
- Patients weight in kg X 30 (If in 30mg/kg cohort) = total dose in mg required
- Patients weight in kg X 10 (If in 10mg/kg cohort) = total dose in mg required

4. **Dissolve the contents of the vial in 50mls of sterile water**

- 1ml of the reconstituted solution contains 30mg of 5-ALA HCL

5. **Divide the total dose required in mg by 30.**

Answer = volume of reconstituted solution needed to give total dose in mg

i.e. the volume to give to the patient (round up or down to nearest ml)

N.B. for some patients more than 1 vial may be required

Additional information on 5-ALA

Aim of the trial

The aim of the glisten trial is to see if 5 ALA can detect malignant spread within the lymph nodes surrounding the bowel during a patient's surgery. 5ALA is preferentially taken up into malignant cells. During the operation when blue light from the laparoscope is shone onto the bowel and surrounding tissue any malignant cells should glow red.

The purpose of this phase of the trial is to find the lowest dose of 5-ALA that causes the cancer and any spread to lymph nodes to glow. To do this different doses of 5-ALA will be given to different cohorts of participants.

If 5 ALA is able to detect malignant spread accurately it may be used in the future to guide how much tissue should be removed during bowel cancer operations.

Treatment of patients on the ward following administration of 5ALA

After administration of 5-ALA, exposure of eyes and skin to strong light sources (e.g. operating illumination, direct sunlight or brightly focused indoor light) should be avoided for 48 hours. Patients should be prevented from going outside in sunny weather conditions; the ward environment is suitable. During the operation patient's eyes and skin will be protected from the operating lights, using standard methods such as sterile drapes and tape to keep their eyes closed.

5-ALA Routine blood tests including Urea and Electrolytes and Liver Function Tests will be performed on a daily basis for 5 days post-operatively

Adverse Effects N.B. Likely to only occur within 48hrs of administration of the drug

- Nausea
- Vomiting
- Tachycardia
- Hypotension
- Transiently deranged LFT's
- Photosensitivity (see above)

Medication to avoid with 5-ALA

Medicines to avoid before participation on the study and for 30 days following administration of 5 ALA

- Medicines known to have a **photosensitising effect**
    - **tetracylines** (e.g. doxycycline, minocycline and oxytetracycline)
    - **sulphonamides** (e.g. Antibiotics - sulfadiazine, trimethoprim, sulfasalazine, Antidiabetic drugs - glipizide, glimepiride, gliclazide, Thiazide diuretics - hydrochlorthiazide, indapamide, metalozone, Loop diuretics - frusemide, Carbonic anhydrase inhibitors - acetazolamide, COX2 inhibitors - celecoxib)
    - **quinolones** (e.g. ciprofloxacin, levofloxacin)

- Medicines associated with **acute porphyria**
    - **Diclofenac**

    - **Barbiturates**
    - **Carbamazepine**
    - **Phenytoin**

- Medicines associated with **hepatic or renal dysfunction**
    - **NSAIDs**
    - **ACE-inhibitors**
    - **Loop diuretics**
    - **Phenytoin**

- Medicine containing **hypericin extracts** (e.g. St John's wort)

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