Chemotherapy Protocol

HAIRY CELL LEUKEMIA

CLADRIBINE (SC)

Regimen

- HCL – Cladribine (SC)

Indication

- Hairy cell leukemia

Toxicity

Drug	Adverse Effect
Cladribine	Skin rash, fever, myelosuppression, neurotoxicity

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

Patients treated with cladribine carry a lifelong risk of transfusion associated graft versus host disease (TA-GVHD). Where blood products are required these patients must receive only irradiated blood products for life. Local blood transfusion departments must be notified as soon as the decision to treat is made and the patient must be issued with an alert card to carry with them at all times.

Monitoring

Drugs

- FBC, LFTs and U&Es prior to initiating treatment

Dose Modifications

The dose modifications listed are for haematological, liver and renal function and some drug specific toxicities only. Dose adjustments may be necessary for other toxicities as well.

In principle all dose reductions due to adverse drug reactions should not be re-escalated in subsequent cycles without consultant approval. It is also a general rule for chemotherapy that if a third dose reduction is necessary treatment should be stopped.

Please discuss all dose reductions / delays with the relevant consultant before prescribing, if appropriate. The approach may be different depending on the clinical circumstances.

Haematological

No pre-treatment dose reductions or delays should be made for anaemia, neutropenia or thrombocytopenia.

Hepatic Impairment

No information available

Renal Impairment

The potential risks and benefits of cladribine should therefore be carefully considered before treatment is commenced in any patient with renal impairment (CrCl less than or equal to 50ml/min) and it should only be used with caution and close monitoring. Alternatives such as rituximab or interferon may be considered until renal function normalises. Discuss with the relevant consultant.

Other

Dose reductions or interruptions in therapy are not necessary for those toxicities that are considered unlikely to be serious or life threatening. For example, alopecia, altered taste or nail changes.

Regimen

5 day cycle for 1 cycle

Drug	Dose	Days	Administration
Cladribine (Litak)	0.14mg/kg	1, 2, 3, 4, 5	Subcutaneous injection

Dose Information

- Cladribine will be dose banded according to the agreed national bands (2mg/ml)

Administration Information

Extravasation

- Cladribine – neutral

Other

- Each subcutaneous dose should be injected as a single injection into abdominal tissue at approximately 24hour intervals. Up to 7ml may be injected into one site and there is no need to split the daily dose into 2 injections, unless preferred.

- Allow the injection to warm to room temperature, then inject the dose slowly (over approximately 1 minute) and massage the injection site smoothly to distribute the volume.

Additional Therapy

- No antiemetics are required with cladribine

- Allopurinol 300mg once a day oral for 7 days oral

- Anti-infective prophylaxis starting on day 6 and continued until the lymphocytes are above $1x10^9$/L (this may take years post treatment)

    - aciclovir 400mg twice a day oral
    - co-trimoxazole 960mg once a day on Monday, Wednesday and Friday only oral

- Mouthwashes according to local or national policy on the treatment of mucositis.

- Gastric protection with a proton pump inhibitor or a H_2 antagonist may be considered in patients considered at high risk of GI ulceration or bleed.

Addition Information

- The Litak brand is the only brand that is licensed for subcutaneous administration

Coding

- Procurement –

- Delivery –

References
1. von Rohr A et al. Treatment of hairy cell leukaemia with cladribine by subcutaneous bolus injection: a phase II study, Annals of Oncology 2002; 13:1641-1649.
2. Else M, Dearden CE, Matutes E et al. Long term follow up of 233 patients with hairy cell leukemia treated initially with pentostatin or cladribine at a median of 16 years from diagnosis. Br J Haem 2009; 145 (6): 733-740

REGIMEN SUMMARY

Cladribine (SC)

Day 1

1 Warning – Check blood transfusion status
Administration Instructions
Patients treated with cladribine carry a lifelong risk of transfusion associated graft versus host disease.
Where blood products are required these patients must receive ONLY IRRADIATED BLOOD PRODUCTS for life.
Ensure transfusion departments are notified and the patient has been issued with an alert card

2. Cladribine 0.14mg/kg subcutaneous injection
Administration Instructions
Each subcutaneous dose should be injected as a single injection into abdominal tissue at approximately 24hour intervals. Up to 7ml may be injected into one site and there is no need to split the daily dose into 2 injections.

Allow the injection to warm to room temperature, then inject the dose slowly (over approximately 1 minute) and massage the injection site smoothly to distribute the volume.

Day 2, 3, 4, 5

3. Cladribine 0.14mg/kg subcutaneous injection
Administration Instructions
Each subcutaneous dose should be injected as a single injection into abdominal tissue at approximately 24hour intervals. Up to 7ml may be injected into one site and there is no need to split the daily dose into 2 injections unless preferred.

Allow the injection to warm to room temperature, then inject the dose slowly (over approximately 1 minute) and massage the injection site smoothly to distribute the volume.

Take Home Medicines (day 1 only)

2. Aciclovir 400mg twice a day for 28 days oral
Administration Instructions
Start on day 6 of the cycle

3. Co-trimoxazole 960mg once a day on Monday, Wednesday and Friday for 28 days oral
Administration Instructions
Start on day 6 of the cycle

4. Allopurinol 300mg once a day for 7 days oral

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1	March 2017	None	Dr Deborah Wright Pharmacist	Dr Andrew Duncombe Consultant Haematologist

This chemotherapy protocol has been developed as part of the chemotherapy electronic prescribing project. This was and remains a collaborative project that originated from the former CSCCN. These documents have been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust
NHS Isle of Wight
Portsmouth Hospitals NHS Trust
Salisbury Hospital NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
Western Sussex Hospitals NHS Foundation Trust

All actions have been taken to ensure these protocols are correct. However, no responsibility can be taken for errors that occur as a result of following these guidelines.