

Chemotherapy Protocol

Chronic Lymphocytic Leukaemia

Chlorambucil (7 day)

**There are several versions of this protocol each using a different dose or cycle length.
Please check you have the correct version**

Regimen

- CLL – Chlorambucil (7 day)

Indication

- For the treatment of CLL in patients of lower performance status

Toxicity

Drug	Adverse Effect
Chlorambucil	Neutropenia, thrombocytopenia, anaemia, nausea, vomiting, diarrhoea, mouth ulceration, rash

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

Monitoring

- FBC on day one of the cycle
- U&Es and LFTs at baseline, then as clinically indicated.

Dose Modifications

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

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

Dose modifications for haematological toxicity in the table below are for general guidance only. Always refer to the responsible consultant as any dose reductions or delays will be dependent on clinical circumstances and treatment intent.

Consider blood transfusion if the patient is symptomatic of anaemia or where the haemoglobin is less than 8g/dL (80g/L).

Neutrophils ($\times 10^9/L$)		Platelets ($\times 10^9/L$)	Chlorambucil Dose
more than 1	and / or	more than 75	100%
0.5 - 1	and / or	50 - 75	Delay treatment for one week. If counts recover treatment can be re-started. If the counts take between 8-14 days to recover, treatment may be re-started with a 50% dose reduction
less than 0.5	and / or	less than 50	Delay treatment until the counts have recovered, the restart using a 50% dose reduction

Hepatic Impairment

Patients with hepatic impairment should be closely monitored for signs and symptoms of toxicity.

Since chlorambucil is primarily metabolized in the liver, dose reduction should be considered in patients with severe hepatic impairment. However, there are insufficient data in patients with hepatic impairment to provide a specific dosing recommendation.

Renal Impairment

Dose adjustment is not considered necessary in renal impaired patients.

Patients with evidence of impaired renal function should be carefully monitored as they are prone to additional myelosuppression.

Regimen

28 day cycle until disease progression or intolerance (12 cycles will be set in Aria)

Drug	Dose	Days	Administration
Chlorambucil	10mg/m ²	1-7 (inclusive)	Oral

Dose Information

- Chlorambucil is available as 2mg film-coated tablets.
- The dose will be rounded to the nearest 2mg (up if halfway)

Administration Information

- Chlorambucil should be swallowed whole on an empty stomach either one hour before meals or three hours after.

- The daily dose may be divided into three (morning, noon and night) if nausea or vomiting is problematic.
- The film-coated tablets should not be crushed or dissolved prior to administration.

Additional Information

- The National Patient Safety Alert on oral chemotherapy (NPSA/2008/RRR001) must be followed in relation to chlorambucil.
- It must be made clear to all staff, including those in the community, that chlorambucil is given as a short course that is repeated and should only be prescribed under the supervision of a consultant haematologist.

Coding

- Procurement – X
- Delivery – X

References

1. Vidal L, Gurion R, Ram R et al. Chlorambucil for the treatment of patients with chronic lymphocytic leukemia (CLL). A systematic review and meta-analysis of randomized trials. Leuk Lymphoma 2016; 57 (9): 2047-57.

REGIMEN SUMMARY

Chlorambucil (7 day)

Cycle 1

Day 1, 2, 3, 4, 5, 6, 7

1. Chlorambucil 10mg/m² once a day for 7 days oral

Administration Information
Oral chemotherapy

Swallow whole, do not crush or chew. Take on an empty stomach either one hour before food or three hours after.

The daily dose may be divided into three (morning, noon and night) if adverse effects such as nausea and vomiting occur.

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

Cycle 2 onwards

Day 1, 2, 3, 4, 5, 6, 7

1. Chlorambucil 10mg/m² once a day for 7 days oral

Administration Information
Oral chemotherapy

Swallow whole, do not crush or chew. Take on an empty stomach either one hour before food or three hours after.

The daily dose may be divided into three (morning, noon and night) if adverse effects such as nausea and vomiting occur.

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1	February 2017	None	Dr Deborah Wright Pharmacist	Dr Helen Dignum 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 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.