

SHARED CARE PROTOCOL: LAMIVUDINE

NHS GREATER GLASGOW AND CLYDE

NB: This document should be read in conjunction with the current Summary of Product Characteristics (SPC)

DRUG AND INDICATION:

Generic drug name:	Lamivudine
Formulation:	Film-coated tablet containing 100mg lamivudine
Intended indication:	Chronic hepatitis B infection in adults with compensated liver disease with evidence of active viral replication, liver inflammation and/or fibrosis.
Status of medicine or treatment:	Licensed medicine Formulary medicine

RESPONSIBILITIES OF ACUTE CARE/SPECIALIST SERVICE (CONSULTANT):

- Undertake baseline investigations/monitoring and initiate treatment or ask GP to initiate treatment.
- If appropriate, ensure that the patient has an adequate supply of medication (usual minimum of 28 days) until the shared care arrangement are in place
- Dose adjustments

Acute care/specialist service will provide the GP with:

- An initiation letter (which includes diagnosis, relevant clinical information, treatment plan, duration of treatment before consultant review)
- Letter of outpatient consultations, ideally within 14 days of seeing the patient

Acute care/specialist will provide the patient with relevant drug information to enable:

- Understanding of potential side effects
- Understanding of the role of monitoring

RESPONSIBILITIES OF PRIMARY CARE (GENERAL PRACTITIONER):

- To prescribe in collaboration with the acute specialist according to this protocol
- To ensure the continuous prescription of medication until treatment is discontinued at specialist instruction
- Liaison with the hospital specialist in the event of symptoms or abnormal results thought due to this treatment

RESPONSIBILITIES OF PATIENT:

- To attend hospital and GP clinic appointments. Failure to attend appointments may result in medication being stopped
- To report adverse effects to their specialist
- To request repeat prescriptions from the GP prior to current prescription finishing

ADDITIONAL RESPONSIBILITIES:

- None

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CAUTIONS:

- Renal impairment: dose adjustment recommended for patients if creatinine clearance < 50 ml/min, (see SPC).
- Exacerbations of hepatitis
- Patients with decompensated liver disease
- Lactic acidosis
- Pregnancy and breastfeeding
- HIV co-infection. Used at higher dose with other anti-retroviral drugs

CONTRAINDICATIONS:

- Hypersensitivity to the active substance or to any of the excipients

TYPICAL DOSAGE REGIMEN:

Route of administration:	Oral administration
Recommended starting dose:	100mg every 24 hours with or without food
Titration of dose:	None
Maximum dose:	100 mg daily
Conditions requiring dose adjustment:	Renal Impairment
Usual response time:	Variable, depends on HBV viral load and host factors
Duration of treatment	Treatment is usually for many years. Treatment may be discontinued if there is HBsAg loss or HBeAg seroconversion.

All dose adjustments or discontinuations will be decided in acute care and directions given in medical letter to the GP

SIGNIFICANT DRUG INTERACTIONS:

- Do not use with emtricitabine for HIV

UNDESIRABLE EFFECTS:

ADR details	Management of ADR
Weakness, fatigue, headache, dizziness, nausea, vomiting, diarrhoea, abdominal pain.	These are the most common side-effects and usually mild
Muscle disorders, including elevations of CPK, myalgia and cramps	

The above list should not be considered exhaustive. For further documented ADRs and details of likelihood etc, see Summary of Product Characteristics or BNF.

BASELINE INVESTIGATIONS (ACUTE SECTOR):

- Urea and electrolytes, eGFR, LFTs, HIV test.

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MONITORING (PRIMARY CARE):

- No monitoring is to be undertaken in Primary Care

MONITORING (ACUTE SECTOR):

- The following monitoring is to be undertaken in Acute Care

Monitoring Parameters	Frequency	Laboratory results	Action to be taken
U&Es, LFTs	Every 3-6 months		
Hepatitis B Viral load	Every 3-6 months		
Hepatitis B e markers	Every 6 months		

PHARMACEUTICAL ASPECTS:

- Shelf life 2 years
- Store below 30°C (tablets)

COST:

- Approximate cost for 1 patient per year is £936 (BNF accessed online 02/06/15)
- PLEASE NOTE: All medicines included in a shared care protocol that meet the criteria for a "high cost expensive medicine" and are prescribed in accordance with the shared care protocol are automatically accounted for in the "high cost/ expensive medicines list" for budget-setting purposes. No additional action is therefore required by GPs to request funding. For those medicines which are the subject of a shared care protocol but which do not meet the high cost expensive medicines criteria, transfer of prescribing costs will be considered as appropriate.

INFORMATION FOR COMMUNITY PHARMACIST:

- None of note

ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION:

Name	Designation	Acute Site	Department phone number
Dr David Bell Dr Erica Peters	Consultant in Infectious Diseases	Brownlee Centre, Gartnavel General Hospital	0141 301 7489
Prof Peter R Mills Dr Matt Priest	Consultant Gastroenterologist	Gartnavel General Hospital	0141 301 7489
Dr Stephen Barclay Dr Adrian Stanley Dr Ewan Forrest	Consultant Gastroenterologist	Glasgow Royal Infirmary	0141 211 4911
Dr Judith Morris Dr Shouren Datta	Consultant Gastroenterologist	Southern General	0141 201 2177
Dr Saeed Sarwar	Consultant Gastroenterologist	Victoria Infirmary	0141 347 8320
Dr Mathis Heydtmann	Consultant Gastroenterologist	Inverclyde Royal Hospital	01475 633 777

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Dr James McPeake	Consultant Gastroenterologist	Royal Alexandra Hospital	0141 314 6850
Dr Rizwana Hamid	Consultant Gastroenterologist	Vale of Leven Hospital	01389 817 239
Ysobel Gourlay Kathryn Brown	BBV Specialist Pharmacists	Gartnavel General Hospital	0141 211 3383 0141 211 3317

SUPPORTING DOCUMENTATION:

- NHS GGC Hepatitis B Treatment Guideline, December 2013.
<http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCclinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Hepatitis%20B%20Infection%20Assessment%20and%20Management%20in%20Adults.pdf>