

# SHARED CARE PROTOCOL: ENTECAVIR▼

NHS GREATER GLASGOW AND CLYDE

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

## DRUG AND INDICATION:

<b>Generic drug name:</b>	<b>Entecavir</b>
<b>Formulations:</b>	Film-coated tablet containing 0.5mg or 1mg entecavir.
<b>Intended indication:</b>	Chronic hepatitis B infection in adults with compensated liver disease with evidence of active viral replication, liver inflammation and/or fibrosis.
<b>Status of medicine or treatment:</b>	Licensed medicine Formulary medicine for above indication.

## 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 arrangements 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
- In the community Entecavir is distributed via Alcura (tel 01420 543400). Community pharmacies can order direct from the company with delivery the next working day if order is placed before 4pm Monday to Friday.
- 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

### CAUTIONS:

- Renal impairment: dosage adjustment is recommended for patients with creatinine clearance < 50 ml/min, (see SPC).
- Exacerbations of hepatitis
- Patients with decompensated liver disease: a higher rate of serious hepatic adverse events
- Lactic acidosis and severe hepatomegaly with steatosis
- Patients with Lamivudine-resistance or previous Lamivudine exposure
- Liver transplant recipients
- Co-infection with hepatitis C or D
- Human immunodeficiency virus (HIV)/HBV co-infected patients
- Pregnancy and breastfeeding

### CONTRAINDICATIONS:

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

### TYPICAL DOSAGE REGIMEN:

<b>Route of administration:</b>	Oral administration
<b>Recommended starting dose:</b>	<ul style="list-style-type: none"><li>Patients not previously treated with nucleoside analogues: 0.5mg every 24 hours at least 2 hours before or after food</li><li>In lamivudine refractory patients, 1mg every 24 hours at least 2 hours before or after food.</li></ul>
<b>Titration of dose:</b>	Not applicable
<b>Maximum dose:</b>	1mg daily
<b>Adjunctive treatment regimen:</b>	
<b>Conditions requiring dose adjustment:</b>	Lamivudine refractory patients with compensated liver disease. Renal impairment – see SPC
<b>Usual response time:</b>	Variable, depends on HBV viral load and host factors
<b>Duration of treatment</b>	Treatment with entecavir 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 specified in a medical letter to the GP**

### SIGNIFICANT DRUG INTERACTIONS:

- None

### UNDESIRABLE EFFECTS:

- Document the likely adverse drug reactions and the suggested management of them in the table below.

ADR details (where possible indicate if common, rare or serious)	Management of ADR
Insomnia [common]	Can usually be managed symptomatically and do not usually require treatment discontinuation
Headache, dizziness, somnolence [common]	
Vomiting, diarrhoea, nausea, dyspepsia [common]	
Elevated transaminases [common]	
Fatigue [common]	
Rash, [uncommon]	

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 and serum phosphate.

### 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 6-12 months		

### PHARMACEUTICAL ASPECTS:

- Shelf life 2 years
- After opening, solution can be used up to the expiry date on the bottle.
- Store below 30°C
- Store bottle in outer carton to protect from light (solution)

### COST:

- Approximate cost for 1 patient per year is £4359 (BNF accessed online 02/06/15)

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- 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 PHARMACISTS:

- In the community entecavir is distributed via Alcura (tel 01420 543400). Community pharmacies can order direct from the company with delivery the next working day if order is placed before 4pm Monday to Friday.

### ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION:

- Contact details for suitable persons within acute care to get further information from (including the likely consultants who will be initiating the treatment)

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
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/GGC%20ClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Hepatitis%20B%20Infection%20Assessment%20and%20Management%20in%20Adults.pdf>