contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

SMC No. 1271/17

The *Scottish Medicines Consortium* has advised (April 2018) that sofosbuvir with velpatasvir (*Epclusa*®) is accepted for restricted use within NHS Scotland for the treatment of chronic hepatitis C virus (HCV) infection in adults with genotype 1 or 4. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Tablet

CAUTIONARY AND ADVISORY LABELS 25

- Epclusa (Gilead Sciences International Ltd) ▼
  Velpatasvir 100 mg, Sofosbuvir 400 mg Epclusa 400mg/100mg tablets | 28 tablet PoM £12,993.33

Sofosbuvir with velpatasvir and voxilaprevir

19-Mar-2018

The properties listed below are those particular to the combination only. For the properties of the components please consider, sofosbuvir p. 665.

- **INDICATIONS AND DOSE**

Chronic hepatitis C infection (specialist use only)

- BY MOUTH
- Adult: 1 tablet once daily, for duration of treatment, consult product literature

DOSE ADJUSTMENTS DUE TO INTERACTIONS

- Manufacturer advises reduce dose of concurrent H_2-receptor antagonist if above a dose comparable to famotidine 40 mg twice daily.
- Manufacturer advises reduce dose of concurrent proton pump inhibitor if above a dose comparable to omeprazole 20 mg.

- **CAUTIONS** Hepatitis B co-infection
- **INTERACTIONS** → Appendix 1: sofosbuvir • velpatasvir • voxilaprevir
- **HEPATIC IMPAIRMENT** Manufacturer advises avoid in moderate to severe impairment.
- **PATIENT AND CARER ADVICE**

Vomiting Manufacturer advises if vomiting occurs within 4 hours of administration, an additional dose should be taken.

- **NATIONAL FUNDING/ACCESS DECISIONS**

NICE decisions

- **Sofosbuvir–velpatasvir–voxilaprevir for treating chronic hepatitis C (February 2018)** NICE TA507

Sofosbuvir with velpatasvir and voxilaprevir is recommended as an option for treating adults with chronic hepatitis C infection:

- of genotype 1 to 6 with or without compensated cirrhosis (previously treated with direct-acting antivirals)—recommended for 12 weeks, *or*
- of genotype 3 with or without compensated cirrhosis (no treatment history with direct-acting antivirals)—recommended for 8 weeks, **and**
- the manufacturer provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit.

Patients whose treatment was started within the NHS before this guidance was published should have the option to continue treatment, without change to their funding arrangements, until they and their NHS clinician consider it appropriate to stop.

www.nice.org.uk/guidance/ta507

Scottish Medicines Consortium (SMC) decisions

SMC No. 1317/18

The *Scottish Medicines Consortium* has advised (April 2018) that sofosbuvir with velpatasvir and voxilaprevir (*Vosevi*®) is accepted for restricted use within NHS Scotland for the treatment of chronic hepatitis C virus (HCV) infection in adults who:

- have failed to achieve a sustained virologic response (SVR) with a direct-acting anti-viral (DAA), **or**
- are DAA-naive, have genotype 3 (GT3) HCV infection, with or without cirrhosis, and are suitable for treatment with an eight-week course.

This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Tablet

CAUTIONARY AND ADVISORY LABELS 21, 25

- Vosevi (Gilead Sciences International Ltd) ▼
  Velpatasvir 100 mg, Voxilaprevir 100 mg, Sofosbuvir 400 mg Vosevi 400mg/100mg/100mg tablets | 28 tablet PoM £14,942.33

ANTIVIRALS › PROTEASE INHIBITORS, HEPATITIS

Glecaprevir with pibrentasvir

25-Oct-2017

- **INDICATIONS AND DOSE**

Chronic hepatitis C (specialist use only)

- BY MOUTH
- Adult: 300/120 mg once daily, for duration of treatment, consult product literature

DOSE EQUIVALENCE AND CONVERSION

- Dose expressed as x/y mg glecaprevir/pibrentasvir.

IMPORTANT SAFETY INFORMATION

HEPATITIS B INFECTION

Cases of hepatitis B reactivation, sometimes fatal, have been reported in patients co-infected with hepatitis B and C viruses; manufacturer advises to assess patients for hepatitis B prior to initiation of therapy and manage according to current clinical guidelines.

MHRA/CHM ADVICE: DIRECT-ACTING ANTIVIRALS TO TREAT CHRONIC HEPATITIS C: RISK OF INTERACTION WITH VITAMIN K ANTAGONISTS AND CHANGES IN INR (JANUARY 2017)

An EU-wide review has identified that changes in liver function, secondary to hepatitis C treatment with direct-acting antivirals, may affect the efficacy of vitamin K antagonists; the MHRA has advised that INR should be monitored closely in patients receiving concomitant treatment.

MHRA/CHM ADVICE: DIRECT-ACTING ANTIVIRALS FOR CHRONIC HEPATITIS C: RISK OF HYPOGLYCAEMIA IN PATIENTS WITH DIABETES (DECEMBER 2018)

Rapid reduction in hepatitis C viral load during direct-acting antiviral therapy for hepatitis C may improve glucose metabolism in patients with diabetes and result in symptomatic hypoglycaemia if diabetic treatment is continued at the same dose.

The MHRA advises healthcare professionals:

- to monitor glucose levels closely in patients with diabetes during direct-acting antiviral therapy for hepatitis C, especially within the first 3 months of treatment and modify diabetic medication or doses when necessary;
- to be vigilant for changes in glucose tolerance and advise patients of the risk of hypoglycaemia;