**Scottish Medicines Consortium (SMC) decisions**
SMC No. 1203/17
The *Scottish Medicines Consortium* advises (January 2017) that *Zepatier*® (elbasvir with grazoprevir) is accepted for use within NHS Scotland for the treatment of chronic hepatitis C in adults with genotype 1a, 1b 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 3
ELECTROLYTES: May contain Sodium
- **Zepatier** (Merck Sharp & Dohme Ltd) ▼
  **Elbasvir 50 mg, Grazoprevir 100 mg** Zepatier 50mg/100mg tablets | 28 tablet PoM £12,166.67

## ANTIVIRALS › NON-STRUCTURAL PROTEIN 5A INHIBITORS

# Ombitasvir with paritaprevir and ritonavir

06-May-2020

The properties listed below are those particular to the combination only. For the properties of the components please consider, ritonavir p. 696.

- **INDICATIONS AND DOSE**

**Chronic hepatitis C of genotype 1 (in combination with dasabuvir, with or without ribavirin) | Chronic hepatitis C of genotype 4 (in combination with ribavirin)**
- BY MOUTH
- Adult: 2 tablets once daily for duration of treatment consult product literature, to be taken with food

**IMPORTANT SAFETY INFORMATION**

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 ANTIVIRAL INTERFERON-FREE REGIMENS TO TREAT CHRONIC HEPATITIS C: RISK OF HEPATITIS B REACTIVATION (JANUARY 2017)

An EU-wide review has concluded that direct-acting antiviral interferon-free regimens for chronic hepatitis C can cause hepatitis B reactivation in patients co-infected with hepatitis B and C viruses; the MHRA recommends to screen patients for hepatitis B before starting treatment—patients infected with both hepatitis B and C viruses must be monitored and managed according to current clinical guidelines.

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;
- to inform the healthcare professional in charge of the diabetic care of the patient when direct-acting antiviral therapy is initiated.

- **CONTRA-INDICATIONS** HIV co-infection without suppressive antiretroviral therapy
- **CAUTIONS** Psychiatric disorders · retreatment—efficacy not established
- **INTERACTIONS** → Appendix 1: HIV-protease inhibitors · ombitasvir · paritaprevir
- **SIDE-EFFECTS**
  - **Common or very common** Anaemia · asthenia · insomnia · nausea · pruritus
  - **Rare or very rare** Angioedema
  - **Frequency not known** Depression · suicidal behaviour

  **SIDE-EFFECTS, FURTHER INFORMATION** Side-effects listed are reported when ombitasvir with paritaprevir and ritonavir is used in combination with dasabuvir, with or without ribavirin.
- **CONCEPTION AND CONTRACEPTION** For women of child-bearing potential, exclude pregnancy before initiation of treatment; effective contraception should be used during treatment.
- **PREGNANCY** Manufacturer advises avoid—toxicity in *animal* studies.
- **BREAST FEEDING** Manufacturer advises avoid—present in milk in *animal* studies.
- **HEPATIC IMPAIRMENT** Manufacturer advises avoid in moderate to severe impairment.
- **PATIENT AND CARER ADVICE**

  **Missed doses** If a dose is more than 12 hours late, the missed dose should not be taken and the next dose should be taken at the normal time.
- **NATIONAL FUNDING/ACCESS DECISIONS**

**NICE decisions**
- **Ombitasvir with paritaprevir and ritonavir with or without dasabuvir for treating chronic hepatitis C (November 2015)**
  NICE TA365
  Ombitasvir with paritaprevir and ritonavir with or without dasabuvir is recommended, within its marketing authorisation, as an option for treating genotype 1 or 4 chronic hepatitis C in adults, only if the manufacturer provides it with the discount agreed in the patient access scheme.
  www.nice.org.uk/guidance/ta365

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

**Tablet**
CAUTIONARY AND ADVISORY LABELS 21, 25
EXCIPIENTS: May contain Propylene glycol
- **Viekirax** (AbbVie Ltd) ▼
  **Ombitasvir 12.5 mg, Ritonavir 50 mg, Paritaprevir 75 mg** Viekirax 12.5mg/75mg/50mg tablets | 56 tablet PoM £10,733.33

## ANTIVIRALS › NUCLEOSIDE ANALOGUES

# Ribavirin

27-Aug-2019

## (Tribavirin)

- **INDICATIONS AND DOSE**

**Bronchiolitis**
- BY INHALATION OF AEROSOL, OR BY INHALATION OF NEBULISED SOLUTION
- Child 1-23 months: Inhale a solution containing 20 mg/mL for 12–18 hours for at least 3 days, maximum of 7 days, to be administered via small particle aerosol generator