transplant—risk of rejection · risk of growth retardation in children, the reversibility of which is uncertain—if possible, consider starting treatment after pubertal growth spurt

- **INTERACTIONS** → Appendix 1: ribavirin
- **SIDE-EFFECTS**
  - **Common or very common** Alopecia · anaemia · anxiety · appetite decreased · arrhythmias · arthralgia · arthritis · asthenia · behaviour abnormal · chest pain · chills · concentration impaired · constipation · cough · depression · diarrhoea · dizziness · drowsiness · dry mouth · dysphagia · dyspnoea · ear pain · eye disorders · eye inflammation · eye pain · fever · gastrointestinal discomfort · gastrointestinal disorders · haemorrhage · headaches · hyperthyroidism · hypotension · hypothyroidism · increased risk of infection · influenza like illness · lymphadenopathy · malaise · memory loss · mood altered · muscle complaints · muscle weakness · nasal congestion · nausea · neutropenia · oral disorders · pain · palpitations · peripheral oedema · photosensitivity reaction · respiratory disorders · sensation abnormal · sexual dysfunction · skin reactions · sleep disorders · sweat changes · syncope · taste altered · thirst · throat pain · thrombocytopenia · tinnitus · tremor · vasodilation · vertigo · vision disorders · vomiting · weight decreased
  - **Uncommon** Dehydration · diabetes mellitus · hallucination · hearing loss · hepatic disorders · hypertension · nerve disorders · sarcoidosis · suicidal tendencies · thyroiditis
  - **Rare or very rare** Angina pectoris · angioedema · bone marrow disorders · cardiac inflammation · cerebral ischaemia · cholangitis · coma · congestive heart failure · facial paralysis · hepatic failure (discontinue) · hypersensitivity · intracranial haemorrhage · myocardial infarction · myopathy · pancreatitis · psychotic disorder · pulmonary embolism · retinopathy · seizure · severe cutaneous adverse reactions (SCARs) · systemic lupus erythematosus (SLE) · vasculitis
  - **Frequency not known** Haemolytic anaemia · homicidal ideation · nephrotic syndrome · pure red cell aplasia · renal failure · solid organ transplant rejection · tongue discolouration · ulcerative colitis

  SIDE-EFFECTS, FURTHER INFORMATION Side effects listed are reported when oral ribavirin is used in combination with peginterferon alfa or interferon alfa, consult product literature for details.
- **CONCEPTION AND CONTRACEPTION**
  - With systemic use Exclude pregnancy before treatment in females of childbearing age. Effective contraception essential during treatment and for 4 months after treatment in females and for 7 months after treatment in males of childbearing age. Routine monthly pregnancy tests recommended. Condoms must be used if partner of male patient is pregnant (ribavirin excreted in semen).
  - When used by inhalation Women planning pregnancy should avoid exposure to aerosol.
- **PREGNANCY** Avoid; teratogenicity in *animal* studies.
  - When used by inhalation Pregnant women should avoid exposure to aerosol.
- **BREAST FEEDING** Avoid—no information available.
- **HEPATIC IMPAIRMENT** Avoid oral ribavirin in severe hepatic dysfunction or decompensated cirrhosis.
  Dose adjustments No dosage adjustment required.
- **RENAL IMPAIRMENT** Plasma-ribavirin concentration increased. Manufacturer advises avoid oral ribavirin if estimated glomerular filtration rate less than 50 mL/minute/1.73 m^2—monitor haemoglobin concentration closely.

  Manufacturer advises use intravenous preparation with caution if estimated glomerular filtration rate less than 30 mL/minute/1.73 m^2.
- **MONITORING REQUIREMENTS**
  - When used by inhalation Monitor electrolytes closely. Monitor equipment for precipitation.
  - With systemic use Determine full blood count, platelets, electrolytes, serum creatinine, liver function tests and uric acid before starting treatment and then on weeks 2 and 4 of treatment, then as indicated clinically—adjust dose if adverse reactions or laboratory abnormalities develop (consult product literature). Test thyroid function before treatment and then every 3 months.
  - With oral use Eye examination recommended before treatment. Eye examination also recommended during treatment if pre-existing ophthalmological disorder or if decrease in vision reported—discontinue treatment if ophthalmological disorder deteriorates or if new ophthalmological disorder develops.
- **PRESCRIBING AND DISPENSING INFORMATION** Flavours of oral liquid formulations may include bubble-gum.
- **NATIONAL FUNDING/ACCESS DECISIONS**

  NICE decisions
  - **Peginterferon alfa and ribavirin for chronic hepatitis C (November 2013)** NICE TA300

    Peginterferon alfa in combination with ribavirin is recommended (within the marketing authorisation) as an option for treating chronic hepatitis C in children.
    www.nice.org.uk/TA300
- **LESS SUITABLE FOR PRESCRIBING** Ribavirin inhalation is less suitable for prescribing.

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

Solution for injection

- **Virazole** (Meda Pharmaceuticals Ltd)
  Ribavirin 100 mg per 1 ml Virazole 1.2g/12ml solution for injection vials | 5 vial PoM £3,600.00

Oral solution

CAUTIONARY AND ADVISORY LABELS 21

- **Rebetol** (Merck Sharp & Dohme Ltd)
  Ribavirin 40 mg per 1 ml Rebetol 40mg/ml oral solution | 100 ml PoM £67.08

Capsule

CAUTIONARY AND ADVISORY LABELS 21

- **Ribavirin (Non-proprietary)**
  Ribavirin 200 mg Ribavirin 200mg capsules | 84 capsule PoM £160.69 | 140 capsule PoM £267.81 | 168 capsule PoM £321.38
- **Rebetol** (Merck Sharp & Dohme Ltd)
  Ribavirin 200 mg Rebetol 200mg capsules | 168 capsule PoM £321.38

ANTIVIRALS › NUCLEOTIDE ANALOGUES

Ledipasvir with sofosbuvir

11-Jul-2018

The properties listed below are those particular to the combination only. For the properties of the components please consider, sofosbuvir p. 417.

- **DRUG ACTION** Sofosbuvir is a nucleotide analogue inhibitor and ledipasvir is an HCV inhibitor; they reduce viral load by inhibiting hepatitis C virus RNA replication.

- **INDICATIONS AND DOSE**

Chronic hepatitis C infection (initiated by a specialist)

- BY MOUTH
- Child 12–17 years: 90/400 mg 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