

**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

**All Wales Medicines Strategy Group (AWMSG) decisions**  
AWMSG No. 2936

The *All Wales Medicines Strategy Group* has advised (October 2016) that rilpivirine (*Edurant*®) is recommended as an option for use within NHS Wales in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients from 12 years old to < 18 years old with a viral load  $\leq$  100,000 HIV-1 RNA copies/ml.

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

#### Tablet

CAUTIONARY AND ADVISORY LABELS 3, 21, 25

▶ **Edurant** (Janssen-Cilag Ltd)

Rilpivirine (as Rilpivirine hydrochloride) 25 mg Edurant 25mg tablets | 30 tablet [PoM] £200.27

Combinations available: *Emtricitabine with rilpivirine and tenofovir alafenamide*, p. 453

## ANTIVIRALS > NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS

### Nucleoside reverse transcriptase inhibitors

#### ● SIDE-EFFECTS

- ▶ **Common or very common** Abdominal pain · anaemia (may require transfusion) · asthenia · diarrhoea · dizziness · headache · insomnia · nausea · neutropenia · skin reactions · vomiting
- ▶ **Uncommon** Angioedema · lactic acidosis · pancreatitis
- ▶ **Frequency not known** Immune reconstitution inflammatory syndrome · osteonecrosis

**SIDE-EFFECTS, FURTHER INFORMATION** Osteonecrosis has been reported in patients with advanced HIV disease or following long-term exposure to combination antiretroviral therapy.

#### ● PREGNANCY

**Monitoring** Mitochondrial dysfunction has been reported in infants exposed to nucleoside reverse transcriptase inhibitors in utero; the main effects include haematological, metabolic, and neurological disorders; all infants whose mothers received nucleoside reverse transcriptase inhibitors during pregnancy should be monitored for relevant signs or symptoms.

● **HEPATIC IMPAIRMENT** In general, manufacturers advise caution in patients with chronic hepatitis B or C (increased risk of hepatic side-effects).

- ▶ Child 3 months–11 years (body-weight 30 kg and above): 300 mg twice daily, alternatively 600 mg once daily
- ▶ Child 12–17 years: 300 mg twice daily, alternatively 600 mg once daily

● **INTERACTIONS** → Appendix 1: abacavir

#### ● SIDE-EFFECTS

- ▶ **Common or very common** Appetite decreased · fever · lethargy
  - ▶ **Rare or very rare** Severe cutaneous adverse reactions (SCARs)
  - ▶ **Frequency not known** Hypersensitivity · weight increased
- SIDE-EFFECTS, FURTHER INFORMATION** Life-threatening hypersensitivity reactions have been reported—characterised by fever or rash and possibly nausea, vomiting, diarrhoea, abdominal pain, dyspnoea, cough, lethargy, malaise, headache, and myalgia; less frequently mouth ulceration, oedema, hypotension, sore throat, acute respiratory distress syndrome, anaphylaxis, paraesthesia, arthralgia, conjunctivitis, lymphadenopathy, lymphocytopenia and renal failure; rarely myolysis. Laboratory abnormalities may include raised liver function tests and creatine kinase; symptoms usually appear in the first 6 weeks, but may occur at any time. Discontinue immediately if any symptom of hypersensitivity develops and do not rechallenge (risk of more severe hypersensitivity reaction).

● **ALLERGY AND CROSS-SENSITIVITY** Caution—increased risk of hypersensitivity reaction in presence of HLA-B\*5701 allele.

● **HEPATIC IMPAIRMENT** Manufacturer advises caution in mild impairment; consider avoiding in moderate to severe impairment (no information available).

● **RENAL IMPAIRMENT** Manufacturer advises avoid in end-stage renal disease.

● **PRE-TREATMENT SCREENING** Test for HLA-B\*5701 allele before treatment or if restarting treatment and HLA-B\*5701 status not known.

● **MONITORING REQUIREMENTS** Monitor for symptoms of hypersensitivity reaction every 2 weeks for 2 months.

● **PRESCRIBING AND DISPENSING INFORMATION** Flavours of oral liquid formulations may include banana, or strawberry.

● **PATIENT AND CARER ADVICE** Patients and their carers should be told the importance of regular dosing (intermittent therapy may increase the risk of sensitisation), how to recognise signs of hypersensitivity, and advised to seek immediate medical attention if symptoms develop or before re-starting treatment.

Patients should be provided with an alert card and advised to keep it with them at all times.

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

#### Oral solution

EXCIPIENTS: May contain Propylene glycol

▶ **Ziagen** (ViiV Healthcare UK Ltd)

**Abacavir (as Abacavir sulfate) 20 mg per 1 ml** Ziagen 20mg/ml oral solution sugar-free | 240 ml [PoM] £55.72

#### Tablet

▶ **Abacavir (Non-proprietary)**

**Abacavir (as Abacavir sulfate) 300 mg** Abacavir 300mg tablets | 60 tablet [PoM] £177.60–£177.61

▶ **Ziagen** (ViiV Healthcare UK Ltd)

**Abacavir (as Abacavir sulfate) 300 mg** Ziagen 300mg tablets | 60 tablet [PoM] £208.95

## Abacavir

10-Sep-2018

#### ● INDICATIONS AND DOSE

**HIV infection in combination with other antiretroviral drugs**

#### ▶ BY MOUTH

- ▶ Child 3 months–11 years: 8 mg/kg twice daily (max. per dose 300 mg), alternatively 16 mg/kg once daily (max. per dose 600 mg)
- ▶ Child 3 months–11 years (body-weight 14–20 kg): 150 mg twice daily, alternatively 300 mg once daily
- ▶ Child 3 months–11 years (body-weight 21–29 kg): 150 mg, taken in the morning and 300 mg, taken in the evening, alternatively 450 mg once daily