

haemorrhage · hearing impairment · hyperhidrosis · hypertension · hypotension · hypothyroidism · increased risk of infection · liver disorder · malaise · mood altered · muscle weakness · myalgia · pain in extremity · palpitations · peripheral coldness · peripheral neuropathy · peripheral oedema · psychomotor retardation · psychotic disorder · sensation abnormal · speech impairment · tinnitus · toothache · weight decreased

▶ **Frequency not known** Angioedema · leucopenia · pancreatitis · severe cutaneous adverse reactions (SCARs) · thrombocytopenia

● **ALLERGY AND CROSS-SENSITIVITY** Antiepileptic hypersensitivity syndrome theoretically associated with eslicarbazepine. See under Epilepsy p. 195 for more information.

● **PREGNANCY** Manufacturer advises minimum effective doses and monotherapy if possible—reproductive toxicity in *animal* studies.

**Monitoring** The dose should be monitored carefully during pregnancy and after birth, and adjustments made on a clinical basis.

● **BREAST FEEDING** Manufacturer advises avoid—present in milk in *animal* studies.

● **HEPATIC IMPAIRMENT** Manufacturer advises caution in mild to moderate impairment—limited information; avoid in severe impairment—no information available.

● **RENAL IMPAIRMENT** Manufacturer advises avoid if creatinine clearance less than 30 mL/minute. **Dose adjustments** Manufacturer advises reduce initial dose to 5 mg/kg once daily or 10 mg/kg every other day for 2 weeks, then increase to 10 mg/kg once daily if creatinine clearance 30–60 mL/minute. The dose may be further increased based on individual response.

● **PRE-TREATMENT SCREENING** Test for HLA-B\*1502 allele in individuals of Han Chinese or Thai origin (avoid unless no alternative—risk of Stevens-Johnson syndrome in presence of HLA-B\*1502 allele).

● **MONITORING REQUIREMENTS** Monitor plasma-sodium concentration in patients at risk of hyponatraemia and discontinue treatment if hyponatraemia occurs.

● **PRESCRIBING AND DISPENSING INFORMATION** Switching between formulations Care should be taken when switching between oral formulations. The need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with the patient or their carer, taking into account factors such as seizure frequency and treatment history.

● **PATIENT AND CARER ADVICE**

**Driving and skilled tasks** Manufacturer advises patients and carers should be cautioned on the effects on driving and performance of skilled tasks—increased risk of dizziness, somnolence and visual disorders.

● **NATIONAL FUNDING/ACCESS DECISIONS**

**Scottish Medicines Consortium (SMC) decisions**

SMC No. SMC2087

The *Scottish Medicines Consortium* has advised (February 2019) that eslicarbazepine acetate (*Zebinix*®) is accepted for restricted use within NHS Scotland as adjunctive therapy in patients aged above 6 years with focal seizures with or without secondary generalisation. It is restricted for use in refractory epilepsy in patients who have been heavily pre-treated and remain uncontrolled with existing anti-epileptic drugs.

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

**Oral suspension**

CAUTIONARY AND ADVISORY LABELS 8

▶ *Zebinix* (Eisai Ltd)

Eslicarbazepine acetate 50 mg per 1 ml *Zebinix* 50mg/1ml oral suspension sugar-free | 200 ml [PoM] £56.67

**Tablet**

CAUTIONARY AND ADVISORY LABELS 8

▶ *Zebinix* (Eisai Ltd)

Eslicarbazepine acetate 200 mg *Zebinix* 200mg tablets | 60 tablet [PoM] £68.00 DT = £68.00

Eslicarbazepine acetate 800 mg *Zebinix* 800mg tablets | 30 tablet [PoM] £136.00 DT = £136.00

**Ethosuximide**

● **INDICATIONS AND DOSE**

**Absence seizures | Atypical absence seizures (adjunct) | Myoclonic seizures**

▶ **BY MOUTH**

▶ Child 1 month–5 years: Initially 5 mg/kg twice daily (max. per dose 125 mg), dose to be increased every 5–7 days; maintenance 10–20 mg/kg twice daily (max. per dose 500 mg), total daily dose may rarely be given in 3 divided doses

▶ Child 6–17 years: Initially 250 mg twice daily, then increased in steps of 250 mg every 5–7 days; usual dose 500–750 mg twice daily, increased if necessary up to 1 g twice daily

● **CAUTIONS** Avoid in Acute porphyrias p. 624

● **INTERACTIONS** → Appendix 1: antiepileptics

● **SIDE-EFFECTS** Aggression · agranulocytosis · appetite decreased · blood disorder · bone marrow disorders · concentration impaired · depression · diarrhoea · dizziness · drowsiness · erythema nodosum · fatigue · gastrointestinal discomfort · generalised tonic-clonic seizure · headache · hiccups · leucopenia · libido increased · lupus-like syndrome · mood altered · movement disorders · nausea · nephrotic syndrome · oral disorders · psychosis · rash · sleep disorders · Stevens-Johnson syndrome · vaginal haemorrhage · vision disorders · vomiting · weight decreased

**SIDE-EFFECTS, FURTHER INFORMATION** Blood counts required if features of fever, sore throat, mouth ulcers, bruising or bleeding.

● **PREGNANCY** See also *Pregnancy* in Epilepsy p. 195.

**Monitoring** The dose should be monitored carefully during pregnancy and after birth, and adjustments made on a clinical basis.

● **BREAST FEEDING** Present in milk. Hyperexcitability and sedation reported.

● **HEPATIC IMPAIRMENT** Use with caution.

● **RENAL IMPAIRMENT** Use with caution.

● **PATIENT AND CARER ADVICE**

**Blood disorders** Patients or their carers should be told how to recognise signs of blood disorders, and advised to seek immediate medical attention if symptoms such as fever, mouth ulcers, bruising, or bleeding develop.

**Medicines for Children leaflet: Ethosuximide for preventing seizures** [www.medicinesforchildren.org.uk/ethosuximide-preventing-seizures](http://www.medicinesforchildren.org.uk/ethosuximide-preventing-seizures)

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

**Oral solution**

CAUTIONARY AND ADVISORY LABELS 8

▶ *Ethosuximide* (Non-proprietary)

Ethosuximide 50 mg per 1 ml *Ethosuximide* 250mg/5ml syrup | 200 ml [PoM] £173.00 DT = £173.00

Ethosuximide 250mg/5ml oral solution sugar free sugar-free | 125 ml [PoM] £108.12–£108.13 sugar-free | 250 ml [PoM] £216.25

**Capsule**

CAUTIONARY AND ADVISORY LABELS 8

▶ *Ethosuximide* (Non-proprietary)

Ethosuximide 250 mg *Ethosuximide* 250mg capsules | 56 capsule [PoM] £173.00 DT = £173.00