

● 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.

Patients may need to be maintained on a specific manufacturer's branded or generic zonisamide product.

- **PATIENT AND CARER ADVICE** Children and their carers should be made aware of how to prevent and recognise overheating and dehydration.
Medicines for Children leaflet: Zonisamide for preventing seizures www.medicinesforchildren.org.uk/zonisamide-preventing-seizures

● NATIONAL FUNDING/ACCESS DECISIONS**Scottish Medicines Consortium (SMC) decisions**

SMC No. 949/14

The *Scottish Medicines Consortium* has advised (March 2014) that zonisamide (*Zonegran*®) is accepted for restricted use within NHS Scotland as adjunctive treatment of focal seizures, with or without secondary generalisation, in adolescents and children aged 6 years and above. It is restricted to use on advice from specialists in paediatric neurology or epilepsy.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug. Forms available from special-order manufacturers include: oral suspension, oral solution

Capsule

CAUTIONARY AND ADVISORY LABELS 3, 8, 10

▶ **Zonisamide (Non-proprietary)**

Zonisamide 25 mg Zonisamide 25mg capsules | 14 capsule PoM
£8.82 DT = £7.50

Zonisamide 50 mg Zonisamide 50mg capsules | 56 capsule PoM
£47.04 DT = £39.77

Zonisamide 100 mg Zonisamide 100mg capsules | 56 capsule PoM
£62.72 DT = £4.72

▶ **Zonegran** (Eisai Ltd)

Zonisamide 25 mg Zonegran 25mg capsules | 14 capsule PoM
£8.82 DT = £7.50

Zonisamide 50 mg Zonegran 50mg capsules | 56 capsule PoM
£47.04 DT = £39.77

Zonisamide 100 mg Zonegran 100mg capsules | 56 capsule PoM
£62.72 DT = £4.72

ANTIPILEPTICS > BARBITURATES**Phenobarbital**

10-Mar-2020

(Phenobarbitone)**● INDICATIONS AND DOSE****All forms of epilepsy except typical absence seizures**▶ **BY MOUTH**

▶ Child 1 month–11 years: Initially 1–1.5 mg/kg twice daily, then increased in steps of 2 mg/kg daily as required; maintenance 2.5–4 mg/kg 1–2 times a day

▶ Child 12–17 years: 60–180 mg once daily

▶ INITIALLY BY SLOW INTRAVENOUS INJECTION

▶ Neonate: Initially 20 mg/kg, then (by slow intravenous injection or by mouth) 2.5–5 mg/kg once daily, adjusted according to response.

Status epilepticus▶ **BY SLOW INTRAVENOUS INJECTION**

▶ Neonate: Initially 20 mg/kg, dose to be administered at a rate no faster than 1 mg/kg/minute, then 2.5–5 mg/kg 1–2 times a day.

- ▶ Child 1 month–11 years: Initially 20 mg/kg, dose to be administered at a rate no faster than 1 mg/kg/minute, then 2.5–5 mg/kg 1–2 times a day
- ▶ Child 12–17 years: Initially 20 mg/kg (max. per dose 1 g), dose to be administered at a rate no faster than 1 mg/kg/minute, then 300 mg twice daily

DOSE EQUIVALENCE AND CONVERSION

- ▶ For therapeutic purposes phenobarbital and phenobarbital sodium may be considered equivalent in effect.

- **CAUTIONS** Avoid in Acute porphyrias p. 652 · children · debilitated · history of alcohol abuse · history of drug abuse · respiratory depression (avoid if severe)

CAUTIONS, FURTHER INFORMATION Consider vitamin D supplementation in patients who are immobilised for long periods or who have inadequate sun exposure or dietary intake of calcium.

- **INTERACTIONS** → Appendix 1: antiepileptics

● SIDE-EFFECTS**GENERAL SIDE-EFFECTS**

Agitation · agranulocytosis · anticonvulsant hypersensitivity syndrome · behaviour abnormal · bone disorders · bone fracture · cognitive impairment · confusion · depression · drowsiness · folate deficiency · hepatic disorders · memory loss · movement disorders · nystagmus · respiratory depression · skin reactions

SPECIFIC SIDE-EFFECTS

- ▶ With oral use Hallucination · hypotension · megaloblastic anaemia · severe cutaneous adverse reactions (SCARs) · thrombocytopenia

- ▶ With parenteral use Anaemia · aplastic anaemia · Dupuytren's contracture · hypocalcaemia · irritability · toxic epidermal necrolysis

Overdose For details on the management of poisoning, see Active elimination techniques, under Emergency treatment of poisoning p. 891.

- **ALLERGY AND CROSS-SENSITIVITY** Antiepileptic hypersensitivity syndrome associated with phenobarbital. See under Epilepsy p. 203 for more information.

● PREGNANCY

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

- **BREAST FEEDING** Avoid if possible; drowsiness may occur.

- **HEPATIC IMPAIRMENT** Manufacturer advises caution in mild to moderate impairment; avoid in severe impairment.

- **RENAL IMPAIRMENT** Use with caution.

● MONITORING REQUIREMENTS

- ▶ Plasma-phenobarbital concentration for optimum response is 15–40 mg/litre (60–180 micromol/litre); however, monitoring the plasma-drug concentration is less useful than with other drugs because tolerance occurs.

- **TREATMENT CESSATION** Avoid abrupt withdrawal (dependence with prolonged use).

● DIRECTIONS FOR ADMINISTRATION

- ▶ With oral use For administration by *mouth*, tablets may be crushed.

- ▶ With intravenous use For *intravenous injection*, dilute to a concentration of 20 mg/mL with Water for Injections; give over 20 minutes (no faster than 1 mg/kg/minute).

- **PRESCRIBING AND DISPENSING INFORMATION** The RCPCH and NPPG recommend that, when a liquid special of phenobarbital is required, it is alcohol-free and the following strength is used: 50 mg/5 mL. Switching between formulations Different formulations of oral preparations may vary in bioavailability. Patients should be maintained on a specific manufacturer's product.