

Pregnancy Prevention Programme Pharmacists must ensure that female patients have a patient card—see also *Important safety information*.

- **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

Gastro-resistant capsule

CAUTIONARY AND ADVISORY LABELS 8, 10, 21, 25

- ▶ **Convulex** (Pfizer Ltd) ▼

Valproic acid 150 mg Convulex 150mg gastro-resistant capsules | 100 capsule [PoM] £3.68 DT = £3.68

Valproic acid 300 mg Convulex 300mg gastro-resistant capsules | 100 capsule [PoM] £7.35 DT = £7.35

Valproic acid 500 mg Convulex 500mg gastro-resistant capsules | 100 capsule [PoM] £12.25 DT = £12.25

Vigabatrin

● INDICATIONS AND DOSE

Adjunctive treatment of focal seizures with or without secondary generalisation not satisfactorily controlled with other antiepileptics (under expert supervision)

▶ BY MOUTH

- ▶ **Neonate:** Initially 15–20 mg/kg twice daily, to be increased over 2–3 weeks to usual maintenance dose, usual maintenance 30–40 mg/kg twice daily (max. per dose 75 mg/kg).
- ▶ **Child 1–23 months:** Initially 15–20 mg/kg twice daily (max. per dose 250 mg), to be increased over 2–3 weeks to usual maintenance dose, usual maintenance 30–40 mg/kg twice daily (max. per dose 75 mg/kg)
- ▶ **Child 2–11 years:** Initially 15–20 mg/kg twice daily (max. per dose 250 mg), to be increased over 2–3 weeks to usual maintenance dose, usual maintenance 30–40 mg/kg twice daily (max. per dose 1.5 g)
- ▶ **Child 12–17 years:** Initially 250 mg twice daily, to be increased over 2–3 weeks to usual maintenance dose, usual maintenance 1–1.5 g twice daily

▶ BY RECTUM

- ▶ **Child 1–23 months:** Initially 15–20 mg/kg twice daily (max. per dose 250 mg), to be increased over 2–3 weeks to usual maintenance dose, usual maintenance 30–40 mg/kg twice daily (max. per dose 75 mg/kg)
- ▶ **Child 2–11 years:** Initially 15–20 mg/kg twice daily (max. per dose 250 mg), to be increased over 2–3 weeks to usual maintenance dose, usual maintenance 30–40 mg/kg twice daily (max. per dose 1.5 g)
- ▶ **Child 12–17 years:** Initially 250 mg twice daily, to be increased over 2–3 weeks to usual maintenance dose, usual maintenance 1–1.5 g twice daily

Monotherapy in the management of infantile spasms in West's syndrome (under expert supervision)

▶ BY MOUTH

- ▶ **Neonate:** Initially 15–25 mg/kg twice daily, to be adjusted according to response over 7 days to usual maintenance dose; usual maintenance 40–50 mg/kg twice daily (max. per dose 75 mg/kg).
- ▶ **Child 1 month–1 year:** Initially 15–25 mg/kg twice daily, to be adjusted according to response over 7 days to usual maintenance dose; usual maintenance 40–50 mg/kg twice daily (max. per dose 75 mg/kg)

- **UNLICENSED USE** Granules not licensed for rectal use. Tablets not licensed to be crushed and dispersed in liquid. Vigabatrin doses in BNF publications may differ from those in product literature.
- **CONTRA-INDICATIONS** Visual field defects

- **CAUTIONS** History of behavioural problems · history of depression · history of psychosis

CAUTIONS, FURTHER INFORMATION Vigabatrin may worsen absence, myoclonic, tonic and atonic seizures.

- ▶ **Visual field defects** Vigabatrin is associated with visual field defects. The onset of symptoms varies from 1 month to several years after starting. In most cases, visual field defects have persisted despite discontinuation, and further deterioration after discontinuation cannot be excluded. Product literature advises visual field testing before treatment and at 6-month intervals. Patients and their carers should be warned to report any new visual symptoms that develop and those with symptoms should be referred for an urgent ophthalmological opinion. Gradual withdrawal of vigabatrin should be considered.

- **INTERACTIONS** → Appendix 1: antiepileptics

● SIDE-EFFECTS

- ▶ **Common or very common** Abdominal pain · anaemia · anxiety · arthralgia · behaviour abnormal · concentration impaired · depression · dizziness · drowsiness · eye disorders · fatigue · headache · memory loss · mood altered · nausea · oedema · paraesthesia · speech disorder · thinking abnormal · tremor · vision disorders · vomiting · weight increased
- ▶ **Uncommon** Movement disorders · psychotic disorder · seizure (patients with myoclonic seizures at greater risk) · skin reactions
- ▶ **Rare or very rare** Angioedema · encephalopathy · hallucination · hepatitis · optic neuritis · suicide attempt
- ▶ **Frequency not known** Muscle tone increased

SIDE-EFFECTS, FURTHER INFORMATION **Encephalopathic symptoms** Encephalopathic symptoms including marked sedation, stupor, and confusion with non-specific slow wave EEG can occur rarely—reduce dose or withdraw.

Visual field defects About one-third of patients treated with vigabatrin have suffered visual field defects; counselling and careful monitoring for this side-effect are required.

- **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—manufacturer advises avoid.
- **RENAL IMPAIRMENT**
Dose adjustments Consider reduced dose or increased dose interval if estimated glomerular filtration rate less than 60 mL/minute/1.73 m².
- **MONITORING REQUIREMENTS** Closely monitor neurological function.
- **DIRECTIONS FOR ADMINISTRATION**

- ▶ **With oral use** The contents of a sachet should be dissolved in water or a soft drink immediately before taking. Tablets may be crushed and dispersed in liquid.
- ▶ **With rectal use** Dissolve contents of sachet in small amount of water and administer rectally (unlicensed use).
- **PATIENT AND CARER ADVICE** Patients and their carers should be warned to report any new visual symptoms that develop.

Medicines for Children leaflet: Vigabatrin for preventing seizures www.medicinesforchildren.org.uk/vigabatrin-preventing-seizures

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

Powder

CAUTIONARY AND ADVISORY LABELS 3, 8, 13

- ▶ **Sabril** (Sanofi)

Vigabatrin 500 mg Sabril 500mg oral powder sachets sugar-free | 50 sachet [PoM] £24.60 DT = £24.60