

70 mL/minute/1.73 m²—reduced clearance and longer time to steady-state plasma concentration.

● DIRECTIONS FOR ADMINISTRATION

TOPAMAX® CAPSULES Swallow whole or sprinkle contents of capsule on soft food and swallow immediately without chewing.

● PRESCRIBING AND DISPENSING INFORMATION

Switching between formulations Care should be taken when switching between oral formulations in the treatment of epilepsy. 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 being treated for epilepsy may need to be maintained on a specific manufacturer's branded or generic topiramate product.

● PATIENT AND CARER ADVICE

Medicines for Children leaflet: Topiramate for preventing seizures www.medicinesforchildren.org.uk/topiramate-preventing-seizures

TOPAMAX® CAPSULES Patients or carers should be given advice on how to administer *Topamax® Sprinkle* capsules.

- **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

Oral suspension

▶ Topiramate (Non-proprietary)

Topiramate 10 mg per 1 ml Topiramate 50mg/5ml oral suspension sugar free sugar-free | 150 ml [PoM](#) £129.00 DT = £129.00

Topiramate 20 mg per 1 ml Topiramate 100mg/5ml oral suspension sugar free sugar-free | 280 ml [PoM](#) £195.69 DT = £195.69

Tablet

CAUTIONARY AND ADVISORY LABELS 3, 8

▶ Topiramate (Non-proprietary)

Topiramate 25 mg Topiramate 25mg tablets | 60 tablet [PoM](#) £10.00 DT = £6.12

Topiramate 50 mg Topiramate 50mg tablets | 60 tablet [PoM](#) £36.75 DT = £9.33

Topiramate 100 mg Topiramate 100mg tablets | 60 tablet [PoM](#) £37.54 DT = £14.83

Topiramate 200 mg Topiramate 200mg tablets | 60 tablet [PoM](#) £57.60 DT = £47.57

▶ Topamax (Janssen-Cilag Ltd)

Topiramate 25 mg Topamax 25mg tablets | 60 tablet [PoM](#) £19.29 DT = £6.12

Topiramate 50 mg Topamax 50mg tablets | 60 tablet [PoM](#) £31.69 DT = £9.33

Topiramate 100 mg Topamax 100mg tablets | 60 tablet [PoM](#) £56.76 DT = £14.83

Topiramate 200 mg Topamax 200mg tablets | 60 tablet [PoM](#) £110.23 DT = £47.57

Capsule

CAUTIONARY AND ADVISORY LABELS 3, 8

▶ Topiramate (Non-proprietary)

Topiramate 15 mg Topiramate 15mg capsules | 60 capsule [PoM](#) £26.21 DT = £26.21

Topiramate 25 mg Topiramate 25mg capsules | 60 capsule [PoM](#) £15.45 DT = £12.21

Topiramate 50 mg Topiramate 50mg capsules | 60 capsule [PoM](#) £55.08 DT = £55.08

▶ Topamax (Janssen-Cilag Ltd)

Topiramate 15 mg Topamax 15mg sprinkle capsules | 60 capsule [PoM](#) £14.79 DT = £26.21

Topiramate 25 mg Topamax 25mg sprinkle capsules | 60 capsule [PoM](#) £22.18 DT = £12.21

Topiramate 50 mg Topamax 50mg sprinkle capsules | 60 capsule [PoM](#) £36.45 DT = £55.08

Valproic acid

● INDICATIONS AND DOSE

CONVULEX®

Epilepsy

▶ BY MOUTH

▶ Child 1 month-11 years: Initially 10–15 mg/kg daily in 2–4 divided doses, max. 600 mg daily; usual maintenance 25–30 mg/kg daily in 2–4 divided doses, doses up to 60 mg/kg daily in 2–4 divided doses in infantile spasms; monitor clinical chemistry and haematological parameters if dose exceeds 40 mg/kg daily

▶ Child 12-17 years: Initially 600 mg daily in 2–4 divided doses, increased in steps of 150–300 mg every 3 days; usual maintenance 1–2 g daily in 2–4 divided doses, max. 2.5 g daily in 2–4 divided doses

DOSE EQUIVALENCE AND CONVERSION

▶ *Convulex®* has a 1:1 dose relationship with products containing sodium valproate, but nevertheless care is needed if switching or making changes.

IMPORTANT SAFETY INFORMATION

MHRA/CHM ADVICE: VALPROATE MEDICINES: CONTRA-INDICATED IN WOMEN AND GIRLS OF CHILDBEARING POTENTIAL UNLESS CONDITIONS OF PREGNANCY PREVENTION PROGRAMME ARE MET (APRIL 2018)

Valproate is highly teratogenic and evidence supports that use in pregnancy leads to neurodevelopmental disorders (approx. 30–40% risk) and congenital malformations (approx. 10% risk).

Valproate must not be used in women and girls of childbearing potential unless the conditions of the Pregnancy Prevention Programme are met (see *Conception and contraception*) and only if other treatments are ineffective or not tolerated, as judged by an experienced specialist.

Use of valproate in pregnancy is contra-indicated for migraine prophylaxis [unlicensed] and bipolar disorder; it must only be considered for epilepsy if there is no suitable alternative treatment (see *Pregnancy*).

Women and girls (and their carers) must be fully informed of the risks and the need to avoid exposure to valproate medicines in pregnancy; supporting materials have been provided to use in the implementation of the Pregnancy Prevention Programme (see *Prescribing and dispensing information*). The MHRA advises that:

- GPs must recall all women and girls who may be of childbearing potential, provide the Patient Guide, check they have been reviewed by a specialist in the last year and are on highly effective contraception;
- Specialists must book in review appointments at least annually with women and girls under the Pregnancy Prevention Programme, re-evaluate treatment as necessary, explain clearly the conditions as outlined in the supporting materials and complete and sign the Risk Acknowledgement Form—copies of the form must be given to the patient or carer and sent to their GP;
- Pharmacists must ensure valproate medicines are dispensed in whole packs whenever possible—all packs dispensed to women and girls of childbearing potential should have a warning label either on the carton or via a sticker. They must also discuss risks in pregnancy with female patients each time valproate medicines are dispensed, ensure they have the Patient Guide and have seen their GP or specialist to discuss their treatment and the need for contraception.