NHS Tayside Drug & Therapeutics Committee

Local Protocol for the use of Topiramate in the Prophylaxis of Migraine

1.	**New medicine name:** Topiramate 25mg, 50mg tablets or sprinkle capsules
2.	**Licensed indication(s):** Prophylaxis of migraine headache in adults. Initiation of treatment with topiramate should be restricted to specialist care and treatment should be managed under specialist supervision or shared care arrangements.
3.	**Scottish Medicines Consortium advice:** Topiramate (Topamax®) is accepted for restricted use within NHS Scotland for the prophylaxis of migraine headache in adults. It should be restricted to initiation by specialists and treatment should be managed under specialist supervision or shared care arrangements in patients who have not responded to prophylactic treatment with at least one other agent. **Medicines Advisory Group advice:** Locally, use of topiramate is reserved for patients who have not responded to, cannot tolerate, or have contraindications to established prophylactic treatments (ie beta-blockers, tricyclic antidepressants, pizotifen and sodium valproate). Treatment should be initiated by the Neurology Clinic and patients should be monitored according to the local protocol.
4.*	**Prescriber details:** Treatment must be under the direction of the Neurology Clinic thereafter GPs may prescribe.
5.*	**Criteria for patient selection:** Patients who have not responded to, cannot tolerate, or have contraindications to other established treatments ie beta-blockers, tricyclic antidepressants (off-label), pizotifen, and sodium valproate (off label). Refer to Headache Guidelines in the Tayside Area Prescribing Guide.
6.	**Administration details:** Titration should begin at 25mg at night for one week. The dosage should then be increased in increments of 25mg/day at one-week intervals. The recommended total daily dose is 100mg/day administered in two divided doses. Some patients may experience a benefit at a total daily dose of 50mg/day.
7.	**Contra-indications:** Known hypersensitivity to topiramate or any of the tablet/capsule excipients
8.	**Side-effects/cautions:** refer to SPC for further details. Abrupt withdrawal of topiramate should be avoided, the dose should be reduced gradually over at least two weeks to minimise the possibility of rebound migraine headaches. Patients should be advised to drink plenty of water to avoid dehydration and to reduce the likelihood of developing kidney stones. Topiramate may need to be titrated more slowly in patients with renal impairment and should be used with caution in patients with hepatic impairment. The BNF includes topiramate in the list of unsafe drugs for use in acute porphyrias. Topiramate is teratogenic and therefore should not be used during pregnancy. Women of childbearing potential should be advised to use adequate contraception whilst taking topiramate. Topiramate should not be used during breast feeding. Rarely, topiramate has been associated with acute myopia with secondary angle-closure glaucoma, typically occurring within one month of starting treatment. Choroidal effusions resulting in anterior displacement of the lens and iris have also been reported.

9.*	**Monitoring - response to treatment:** (GP responsibility) Topiramate should be administered for a minimum of 12 weeks. If effective, treatment should be continued for 3-6 months then withdrawn to establish continued need (uninterrupted use of migraine prophylaxis over a year is rarely appropriate). If not effective, treatment should be withdrawn and alternative therapy sought.
10.*	**Monitoring – treatment safety:** (GP responsibility) Patients should be monitored for signs of depression and advised to seek medical help immediately if they have suicidal thoughts. Patients on long-term topiramate should be regularly weighed and monitored for continued weight loss. Discontinuation of treatment should be considered if weight loss greater than 10%. Patients with new onset visual signs or symptoms should have their intra-ocular pressure measured urgently. If it is raised then they should be referred to the Ophthalmology Clinic immediately and topiramate stopped as rapidly as feasible.
11.*	**Written by:** Dr J O'Riordan **Date:** August 2006 **Approved by:** Dr Roberts **Date:** August 2006
12.*	**Review date:** August 2007