

Product Name: XAMATE 50 mg Film-Coated Tablets

Active Substances: Topiramate

Form: 60 Film Coated Tablets

Therapeutic indications: "Epilepsy:

XAMATE monotherapy for adults and children 6 years and older who have been newly diagnosed with epilepsy and who have had general tonic-clonic seizures or partial seizures (with or without secondary general seizures) is indicated as.

XAMATE for the conditions listed below with conventional primary antiepileptic drugs

It is indicated as adjunctive therapy in poorly controlled adults and children over 2 years of age:

Partial crises with or without secondary general crises; Crises and primary general tonic clonic crises caused by Lennox Gastaut Syndrome.

The efficacy and safety of switching from adjunctive therapy to Topiramate monotherapy has not yet been established.

Migraine: XAMATE is indicated for headache prophylaxis caused by migraine in adults. Topiramate

Initiation of treatment should only be with special care and treatment under the supervision of a specialist or through shared care arrangements.

Migraine preventive treatment can be considered in situations such as: Adults who have three or more migraine attacks per month; frequent migraine attacks that significantly affect the patient's daily routine.

Continuing treatment should be evaluated every six months.

The usefulness of XAMATE in the treatment of acute migraine has not been studied."

Posology and method of administration:

"Epilepsy:

a) Monotherapy:

Adults and children over 16:

Titration should start at 25 mg at night for 1 week. The dosage may then be increased at 1 or 2 week intervals in increments of 25 or 50 mg / day administered in two divided doses. if

If the patient cannot tolerate the titration regimen, smaller increments or longer intervals between increments may be used. Dosage and titration rate should be guided by the clinical outcome.

The recommended starting target dose for topiramate monotherapy in adults with newly diagnosed epilepsy is 100 mg / day and the maximum recommended daily dose is 400 mg. An underlying renal disease

These dosing recommendations can be applied to all adults, including the elderly.

Children 6-16 years old:

Treatment of children 6 years and older should begin with 0.5 to 1 mg / kg per night for the first week. The dosage is then administered in two divided doses, in increments of 0.5-1 mg / kg / day for 1 or 2 weeks.

intervals can be increased. If the child cannot tolerate the titration regimen, smaller increments or

Longer intervals between increments may be used. The dose and dose titration rate should be guided by the clinical outcome.

Recommended for topiramate monotherapy in children 6 years of age and older with newly diagnosed epilepsy

The initial target dose range is 3-6 mg / kg / day. Higher doses have been tolerated and rarely 16

Doses up to mg / kg / day have been administered.

b) Assistive Treatment:

Adults and children over 16:

The minimally effective dose as adjunctive therapy is 200 mg / day.

Usual total daily dose is two

It ranges from 200 mg to 400 mg in divided doses. Some patients need up to 800 mg / day dosage

can hear, which is the maximum recommended dosage. Initiation of therapy at a low dose and

It is recommended to switch to an effective dose by titration.

Titration should start at 25 mg per day for a week. Total daily dose then 25-50

It should be increased in mg increments at intervals of one to two weeks and divided into two doses.

must be taken. If the patient cannot tolerate the titration regimen, smaller increments or between increments

longer intervals may be used. Dose titration should be guided by the clinical outcome.

Children 2-16 years old:

The total daily dose of Topiramate recommended as auxiliary treatment is approximately 5-9 mg / kg / day divided into two.

Titration should start at 25 mg at night during the first week. The most suitable clinic

In order to get the response, the dosage should then be increased in 1 or 2 week intervals in increments of 1 -3 mg / kg / day (administered in two divided doses). Dose titration depends on the clinical outcome. should be directed.

Daily doses of up to 30 mg / kg / day have been studied and have been found to be generally well tolerated.

Migraine:

Adults and children over 16:

Titration should start at 25 mg at night for 1 week. Dosage then at 1-week intervals

It should be increased in 25 mg / day increments. If the patient cannot tolerate the titration regimen,

Longer intervals between increments may be used.

Total daily dose of topiramate recommended as the treatment for migraine headache prophylaxis

It is 100 mg / day administered in two divided dosages. Some patients total 50 mg / day daily

can benefit from the dose. More benefits with the administration of doses higher than 100 mg / day

has not been seen. Dosage and titration rate should be guided by the clinical outcome."