Trileptal (oxcarbazepine) - Drug Summary

Novartis Pharmaceuticals Corporation

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Trileptal (oxcarbazepine)

THERAPEUTIC CLASS

Dibenzazepine

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Partial Seizures

Adjunctive Therapy:
Initial: 300mg bid
Titrate: Increase by a max of 600mg/day at weekly intervals
Usual: 1200mg/day

Conversion to Monotherapy:
Initial: 300mg bid
Titrate: Increase by a max of 600mg/day at weekly intervals
Usual: 2400mg/day

Reduce dose and withdraw concomitant antiepileptic drugs over 3-6 weeks, while reaching max oxcarbazepine dose in about 2-4 weeks

Initiation of Monotherapy:
Initial: 300mg bid
Titrate: Increase by 300mg/day every third day
Usual: 1200mg/day

PEDIATRIC DOSAGE & INDICATIONS

Partial Seizures

Adjunctive Therapy:
2-<4 Years:
Initial: 8-10mg/kg/day, not to exceed 600mg/day; may consider 16-20mg/kg for patients <20kg
Titrate: Increase to max maint dose over 2-4 weeks
Max: 60mg/kg/day

4-16 Years:
Initial: 8-10mg/kg/day, not to exceed 600mg/day
Maint: Increase to target dose over 2 weeks
20-29kg: 450mg bid
29.1-39kg: 600mg bid
>39kg: 900mg bid

W/ Epilepsy:
Conversion to Monotherapy:
4-16 Years:
Initial: 8-10mg/kg/day
Titrate: Increase by a max of 10mg/kg/day at weekly intervals

Reduce dose and withdraw concomitant antiepileptic drugs over 3-6 weeks

Initiation of Monotherapy:
4-16 Years:
Initial: 8-10mg/kg/day
Titrate: Increase by 5mg/kg/day every third day

Conversion to/Initiation of Monotherapy:

Maint:
20kg: 600-900mg/day
25-30kg: 900-1200mg/day
35-40kg: 900-1500mg/day
45kg: 1200-1500mg/day
50-55kg: 1200-1800mg/day
60-65kg: 1200-2100mg/day
70kg: 1500-2100mg/day

DOSING CONSIDERATIONS

Renal Impairment
CrCl <30mL/min:
Initial: 1/2 the usual starting dose (300mg/day)
Titrate: Increase slowly

ADMINISTRATION

Oral route

All dosing should be given in a bid regimen
Sus and tabs may be interchanged at equal doses
Take w/ or w/o food

Sus
1. Before use, shake well and prepare dose immediately afterwards
2. Use the supplied oral dosing syringe to withdraw the prescribed amount from the bottle
3. Sus may be mixed in a small glass of water just prior to administration or may be swallowed directly from the syringe
4. Close the bottle and rinse the syringe w/ warm water and allow it to dry thoroughly after each use

HOW SUPPLIED

Sus: 300mg/5mL [250mL]; Tab: 150mg*, 300mg*, 600mg* *scored

WARNINGS/PRECAUTIONS

Clinically significant hyponatremia may develop; consider measurement of serum Na^+ levels during maintenance treatment, particularly if patient is receiving other medications known to decrease serum Na^+ levels (eg, drugs associated w/ inappropriate antidiuretic hormone secretion) or if symptoms indicating hyponatremia develop. Anaphylaxis and angioedema involving the larynx, glottis, lips, and eyelids reported; d/c therapy if any of these reactions develop, start alternative treatment, and do not rechallenge. Caution in patients w/ history of hypersensitivity reactions to carbamazepine; d/c immediately if signs/symptoms of hypersensitivity develop. Serious dermatological reactions (eg, Stevens-Johnson syndrome [SJS], toxic epidermal necrolysis [TEN]) reported; consider discontinuing use and prescribing another antiepileptic drug (AED) if a skin reaction develops. Patients carrying the human leukocyte antigen (HLA)-B*1502 allele may be at increased risk for SJS/TEN; consider testing for presence of HLA-B*1502 allele in patients w/ ancestry in genetically at-risk populations, and avoid use in patients positive for HLA-B*1502 unless benefits clearly outweigh risks. Increased risk of suicidal thoughts or behavior. Withdraw gradually to minimize the potential of increased seizure frequency. Associated w/ CNS-related adverse events (cognitive symptoms, somnolence or fatigue, coordination abnormalities). Drug reaction w/ eosinophilia and systemic symptoms (DRESS)/multiorgan hypersensitivity reported; evaluate immediately if signs/symptoms (eg, rash, fever, lymphadenopathy) are present, and d/c if an alternative etiology cannot be established. Pancytopenia, agranulocytosis, and leukopenia reported; consider discontinuation if any evidence of hematologic events develop. Levels may decrease during pregnancy; monitor patients during pregnancy and through the postpartum period. Associated w/ decreases in T4, without changes in T3 or TSH. Caution w/ severe hepatic impairment.

ADVERSE REACTIONS

Dizziness, somnolence, diplopia, fatigue, N/V, ataxia, abnormal vision, tremor, abnormal gait, dyspepsia, abdominal pain.

DRUG INTERACTIONS

Verapamil, valproic acid, and strong CYP450 inducers (eg, carbamazepine, phenytoin, phenobarbital) may decrease levels. May decrease levels of dihydropyridine calcium antagonists, oral contraceptives (eg, ethinyl estradiol, levonorgestrel), cyclosporine, and felodipine. May increase levels of phenytoin, phenobarbital, and CYP2C19 substrates; may require dose reduction of phenytoin when using oxcarbazepine doses >1200mg/day. Decreased levels w/ AEDs that are CYP450 inducers.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Dibenzazepine; has not been established. Suspected to exert antiseizure effects through blockade of voltage-sensitive Na^+ channels, resulting in stabilization of hyperexcited neural membranes, inhibition of repetitive neuronal firing, and diminution of propagation of synaptic impulses. Also, increased K^+ conductance and modulation of high-voltage activated Ca^{2+} channels may contribute to the anticonvulsant effects.

PHARMACOKINETICS

Absorption: (Tab) Complete. T_{max}=4.5 hrs (median). (Sus) T_{max}=6 hrs (median). **Distribution:** Found in breast milk. 10-monohydroxy derivative (MHD): V_d=49L; plasma protein binding (40%). **Metabolism:** Liver (extensive); reduction by cytosolic enzymes to MHD (active metabolite). MHD: Conjugation w/ glucuronic acid. **Elimination:** Urine (>95%, <1% unchanged), feces (<4%); $T_{1/2}$=2 hrs. MHD: $T_{1/2}$=9 hrs.

ASSESSMENT

Assess for history of hypersensitivity to drug or to carbamazepine, presence of HLA-B*1502 allele, depression, renal/hepatic impairment, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of hyponatremia, angioedema, anaphylactic/hypersensitivity/dermatological reactions, emergence/worsening of depression, suicidal thoughts/behavior, unusual changes in mood/behavior, cognitive/neuropsychiatric events, DRESS, hematologic events, and other adverse reactions. Monitor patients during pregnancy and through the postpartum period.

PATIENT COUNSELING

Advise to report symptoms of low Na^+, and fever to physician. Instruct to d/c and contact physician immediately if signs/symptoms suggesting angioedema develop. Advise to consult physician immediately if experiencing a hypersensitivity reaction, skin reaction, or symptoms suggestive of blood disorders. Warn female patients of childbearing age that concurrent use w/ hormonal contraceptives may render this method of contraception less effective; advise to use additional nonhormonal forms of contraception. Advise of the need to be alert for the emergence/worsening of symptoms of depression, any unusual changes in mood/behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm; instruct to immediately report behaviors of concern to physician. Instruct to use caution if taking alcohol while on therapy. Advise that drug may cause dizziness and somnolence, and not to drive or operate machinery until effects have been determined. Encourage to enroll in the North American Antiepileptic Drug Pregnancy Registry if patient becomes pregnant.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F). (Sus) Use w/in 7 weeks of 1st opening the bottle.

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