Neurontin (gabapentin) - Drug Summary

Parke-Davis Division of Pfizer Inc

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Neurontin (gabapentin)

THERAPEUTIC CLASS

GABA analogue

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Postherpetic Neuralgia

Initial: 300mg single dose on Day 1, then 300mg bid (600mg/day) on Day 2, and 300mg tid (900mg/day) on Day 3
Titrate: May subsequently increase prn up to 600mg tid (1800mg/day)

Partial Seizures

Adjuvant Therapy for Partial Onset Seizures w/ Epilepsy, w/ and w/o Secondary Generalization:

Initial: 300mg tid
Maint: 300-600mg tid
Doses up to 2400mg/day (long-term) and 3600mg/day (short-term) have been well tolerated
Administer tid using 300mg or 400mg caps, or 600mg or 800mg tabs
Dosing intervals should not exceed 12 hrs

PEDIATRIC DOSAGE & INDICATIONS

Partial Seizures

Adjuvant Therapy for Partial Onset Seizures w/ Epilepsy, w/ and w/o Secondary Generalization:

3-11 Years:
Initial: 10-15mg/kg/day in 3 divided doses
Titrate: Increase to recommended maint dose over a period of approx 3 days

3-4 Years:
Maint: 40mg/kg/day in 3 divided doses

5-11 Years:
Maint: 25-35mg/kg/day in 3 divided doses

Doses up to 50mg/kg/day have been well tolerated
Dosing intervals should not exceed 12 hrs

≥12 Years:
Initial: 300mg tid
Maint: 300-600mg tid
Doses up to 2400mg/day (long-term) and 3600mg/day (short-term) have been well tolerated
Administer tid using 300mg or 400mg caps, or 600mg or 800mg tabs
Dosing intervals should not exceed 12 hrs

DOSING CONSIDERATIONS

Renal Impairment
≥12 Years:
CrCl ≥60mL/min: 900-3600mg/day in 3 divided doses
CrCl >30-59mL/min: 400-1400mg/day in 2 divided doses
CrCl >15-29mL/min: 200-700mg single daily dose
CrCl 15mL/min: 100-300mg single daily dose
CrCl <15mL/min: Reduce daily dose in proportion to CrCl

Hemodialysis: Dose adjustment is necessary; see PI

Discontinuation
Dose Reduction/Substitution/Discontinuation: Should be done gradually over a minimum of 1 week

ADMINISTRATION

Oral route

Take w/ or w/o food.
Swallow caps whole w/ water.
If the scored tab is broken to administer a half-tab, take the unused half-tab as the next dose; discard half-tabs that are not used w/in 28 days of breaking the scored tab.

HOW SUPPLIED

Cap: 100mg, 300mg, 400mg; **Sol:** 250mg/5mL [470mL]; **Tab:** 600mg*, 800mg* *scored

WARNINGS/PRECAUTIONS

Drug reaction w/ eosinophilia and systemic symptoms (DRESS)/multiorgan hypersensitivity reported; evaluate immediately if signs/symptoms (eg, fever, lymphadenopathy) are present and d/c if an alternative etiology cannot be established. May cause anaphylaxis and angioedema; d/c and seek immediate medical care if experience signs/symptoms of anaphylaxis or angioedema. May cause significant driving impairment. Somnolence/sedation and dizziness reported. May impair mental/physical abilities. Do not abruptly d/c; may increase seizure frequency. Increases the risk of suicidal thoughts/behavior. Use in pediatric patients w/ epilepsy 3-12 yrs of age is associated w/ the occurrence of CNS-related adverse events. May have tumorigenic potential. Sudden and unexplained deaths reported in patients w/ epilepsy. Lab test interactions may occur. Caution in elderly.

ADVERSE REACTIONS

Dizziness, somnolence, fatigue, peripheral edema, hostility, diarrhea, asthenia, infection, dry mouth, nystagmus, constipation, N/V, ataxia, fever, amblyopia.

DRUG INTERACTIONS

Decreases hydrocodone exposure; consider the potential for alteration in hydrocodone exposure and effect when gabapentin is started or discontinued in a patient taking hydrocodone. Morphine may increase gabapentin concentrations; dose adjustment may be required. Observe for signs of CNS depression (eg, somnolence, sedation, respiratory depression) when used w/ other drugs w/ sedative properties (eg, morphine) because of potential synergy. Decreased bioavailability w/ Maalox; take gabapentin at least 2 hrs following Maalox administration.

PREGNANCY AND LACTATION

Pregnancy: Category C.
Lactation: Caution in nursing.

MECHANISM OF ACTION

GABA analogue; has not been established. Binds w/ high-affinity to the α2-delta subunit of voltage-activated Ca^{2+} channels.

PHARMACOKINETICS

Absorption: Administration of variable doses resulted in different parameters. **Distribution:** Plasma protein binding (<3%); found in breast milk; (150mg IV) V_d=58L. **Elimination:** Renal (unchanged); $T_{1/2}$=5-7 hrs.

ASSESSMENT

Assess for hypersensitivity to the drug, renal impairment, depression, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for DRESS, anaphylaxis, angioedema, somnolence/sedation, dizziness, emergence/worsening of depression, suicidal thoughts/behavior, unusual changes in mood/behavior, development/worsening of tumors, increased seizure frequency (upon abrupt discontinuation), and other adverse reactions.

PATIENT COUNSELING

Instruct to immediately report to physician any rash or other signs/symptoms of hypersensitivity/anaphylaxis, angioedema, emergence/worsening of depression symptoms, any unusual changes in mood/behavior, emergence of suicidal thoughts/behavior, or thoughts of self-harm. Inform that therapy may cause a significant driving impairment, dizziness, somnolence, and other signs/symptoms of CNS depression; advise not to drive a car or operate other complex machinery until patient has gained sufficient experience on therapy. Instruct to notify physician if pregnant/breastfeeding or intending to become pregnant or to breastfeed during therapy; encourage enrollment in the North American Antiepileptic Drug Pregnancy Registry if patient becomes pregnant.

STORAGE

Cap/Tab: 25°C (77°F); excursions permitted to 15-30°C (59-86°F). **Sol:** 2-8°C (36-46°F).

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