Dilantin Capsules (phenytoin sodium) - Drug Summary

Parke-Davis Division of Pfizer Inc

Related Drug Information ▼

Dilantin
(phenytoin)

COMMON BRAND NAMES

Dilantin Infatabs, Dilantin-125, Dilantin

THERAPEUTIC CLASS

Hydantoin

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Epilepsy

Tonic-Clonic (Grand Mal) and Psychomotor (Temporal Lobe) Seizure:
Sus:
Initial: 125mg (1 tsp) tid
Titrate: May increase to 625mg (5 tsp) daily

Generalized Tonic-Clonic (Grand Mal) and Complex Partial (Psychomotor/Temporal Lobe) Seizures and Prevention/Treatment of Neurosurgery-Associated Seizures:
Cap, ER:
Divided Daily Dosing:
Initial: 100mg tid
Maint: 100mg tid-qid
Titrate: May increase up to 200mg tid, if necessary

QD Dosing:
May consider 300mg qd if seizure is controlled on divided doses of three 100mg caps daily
LD (Clinic/Hospital):
Initial: 1g in 3 divided doses (400mg, 300mg, 300mg) at 2-hr intervals
Maint: Start maint dose 24 hrs after LD
Do not give oral loading regimen in patients w/ history of renal/liver disease

Tab, Chewable:
Initial: 100mg (2 tabs) tid
Maint: 300-400mg (6-8 tabs) daily
Titrate: May increase to 600mg (12 tabs) daily

Do not change dose at intervals <7-10 days

PEDIATRIC DOSAGE & INDICATIONS

Epilepsy

Tonic-Clonic (Grand Mal) or Psychomotor (Temporal Lobe) Seizure:
Sus:
Initial: 5mg/kg/day in 2 or 3 equally divided doses
Maint: 4-8mg/kg/day
Max: 300mg/day

Generalized Tonic-Clonic (Grand Mal) and Complex Partial (Psychomotor/Temporal Lobe) Seizures and Prevention/Treatment of Neurosurgery-Associated Seizures:
Cap, ER/Tab, Chewable:
Initial: 5mg/kg/day in 2 or 3 equally divided doses
Maint: 4-8mg/kg/day
Max: 300mg/day

>6 Years: May require the minimum adult dose (300mg/day)

Do not change dose at intervals <7-10 days

DOSING CONSIDERATIONS

Elderly
May require lower or less frequent dosing

Other Important Considerations
May require dose adjustment when switching from product formulated w/ free acid to product formulated w/ Na^+ salt and vice versa

ADMINISTRATION

Oral route

Tab, Chewable
May chew or swallow tab whole
Not for once-a-day dosing
If daily dose cannot be divided equally, give larger dose hs

Sus
Use an accurately calibrated measuring device to ensure accurate dosing

HOW SUPPLIED

Cap, ER: 30mg, 100mg; (Dilantin-125) Sus: 125mg/5mL [237mL]; (Infatabs) Tab, Chewable: 50mg* *scored

CONTRAINDICATIONS

Coadministration with delavirdine.

WARNINGS/PRECAUTIONS

Caution in the interpretation of total phenytoin plasma concentrations with renal/hepatic disease, or in those with hypoalbuminemia. Avoid abrupt withdrawal; may precipitate status epilepticus. May increase risk of suicidal thoughts/behavior; monitor for emergence/worsening of depression, suicidal thoughts/behavior, and/or any unusual changes in mood/behavior. Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS), reported; d/c at 1st sign of rash, unless the rash is clearly not drug-related. Do not resume therapy, and consider alternative therapy if signs/symptoms suggest SJS/TEN. Avoid use as an alternative for carbamazepine in patients positive for HLA-B*1502. Drug reaction with eosinophilia and systemic symptoms (DRESS)/multiorgan hypersensitivity reported; evaluate immediately if signs and symptoms (eg, rash, fever, lymphadenopathy) are present and d/c if an alternative etiology cannot be established. Caution with history of hypersensitivity to structurally similar drugs (eg, carboxamides, barbiturates, succinimides, oxazolidinediones); consider alternatives to therapy. Acute hepatotoxicity (eg, acute hepatic failure) reported; d/c immediately and do not readminister. Hematopoietic complications and lymphadenopathy reported; extended follow-up observation is indicated and every effort should be made to achieve seizure control using alternative antiepileptic drugs in all cases of lymphadenopathy. Decreased bone mineral density and bone fractures reported during chronic use; consider screening and initiating treatment plans as appropriate. Caution with porphyria, hepatic impairment, and in elderly or gravely ill patients. Bleeding disorder in newborns may occur; give vitamin K to mother before delivery and to neonate after birth. Check plasma levels immediately if early signs of dose-related CNS toxicity develop. Hyperglycemia reported; may increase serum glucose levels in diabetics. Not indicated for seizures due to hypoglycemia or other metabolic causes. Not effective for absence (petit mal) seizures; if tonic-clonic (grand mal) and absence (petit mal) seizures are present, combined drug therapy is needed. May produce confusional states at levels sustained above optimal range; reduce dose if plasma levels are excessive, or d/c if symptoms persist. Lab test interactions may occur. (Cap, ER) Do not use if discolored. (Tab, Chewable) Not for qd dosing.

ADVERSE REACTIONS

Rash, nystagmus, ataxia, slurred speech, decreased coordination, somnolence, mental confusion, dizziness, insomnia, transient nervousness, motor twitching, N/V, thrombocytopenia, altered taste sensation, Peyronie's disease.

DRUG INTERACTIONS

See Contraindications. Acute alcohol intake, amiodarone, antiepileptic agents (eg, ethosuximide, felbamate, oxcarbazepine, topiramate), azoles (eg, fluconazole, ketoconazole, itraconazole), capecitabine, chloramphenicol, chlordiazepoxide, disulfiram, estrogens, fluorouracil, fluoxetine, fluvastatin, fluvoxamine, H_2-antagonists (eg, cimetidine), halothane, isoniazid, methylphenidate, omeprazole, phenothiazines, salicylates, sertraline, succinimides, sulfonamides (eg, sulfamethizole, sulfadiazine, sulfamethoxazole-trimethoprim), ticlopidine, tolbutamide, trazodone, and warfarin may increase levels. Anticancer drugs (eg, bleomycin, carboplatin, cisplatin, doxorubicin, methotrexate), carbamazepine, chronic alcohol abuse, diazepam, diazoxide, folic acid, fosamprenavir, nelfinavir, reserpine, rifampin, ritonavir (RTV), St. John's wort, sucralfate, vigabatrin, and theophylline may decrease levels. Administration with preparations that increase gastric pH (eg, supplements or antacids containing calcium carbonate, aluminum hydroxide, and magnesium hydroxide) may affect absorption; do not take at the same time of day. Phenobarbital, sodium valproate, and valproic acid may increase or decrease levels. May impair efficacy of azoles (eg, fluconazole, ketoconazole, voriconazole), corticosteroids, doxycycline, estrogens, furosemide, irinotecan, oral contraceptives, paclitaxel, paroxetine, quinidine, rifampin, sertraline, teniposide, theophylline, and vitamin D. Increased and decreased PT/INR responses reported with warfarin. May decrease levels of active metabolites of albendazole, certain HIV antivirals (eg, efavirenz, lopinavir/RTV, indinavir), anti-epileptic agents (eg, felbamate, topiramate, quetiapine), atorvastatin, chlorpropamide, clozapine, cyclosporine, digoxin, fluvastatin, folic acid, methadone, mexiletine, nifedipine, nimodipine, nisoldipine, praziquantel, simvastatin, and verapamil. May decrease levels of amprenavir (active metabolite) when given with fosamprenavir alone. May increase levels of amprenavir when given with the combination of fosamprenavir and RTV. Resistance to the neuromuscular blocking action of pancuronium, vecuronium, rocuronium, and cisatracurium reported in patients chronically administered phenytoin; monitor closely for more rapid recovery from neuromuscular blockade than expected and for higher infusion rate requirements. Avoid with enteral feeding preparations and/or nutritional supplements.

PREGNANCY AND LACTATION

Category D, not for use in nursing.

MECHANISM OF ACTION

Hydantoin; inhibits seizure activity by promoting Na^+ efflux from neurons, stabilizing the threshold against hyperexcitability caused by excessive stimulation or environmental changes capable of reducing membrane Na^+ gradient. Reduces the maximal activity of the brain stem centers responsible for the tonic phase of tonic-clonic (grand mal) seizures.

PHARMACOKINETICS

Absorption: T_{max}=1.5-3 hrs (tab, chewable/sus), 4-12 hrs (cap, ER). **Distribution:** Plasma protein binding (high); found in breast milk. **Metabolism:** Liver (hydroxylation). **Elimination:** Bile (mostly as inactive metabolites), urine; $T_{1/2}$=22 hrs, 14 hrs (tab, chewable).

ASSESSMENT

Assess for hypersensitivity to the drug, its inactive ingredients, or other hydantoins, alcohol use, hepatic/renal impairment, porphyria, grave illness, seizures due to hypoglycemia or other metabolic causes, absence seizures, any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for hypersensitivity reactions, dermatologic reactions, DRESS/multiorgan hypersensitivity, hepatotoxicity, hematopoietic complications, lymphadenopathy, decreased bone mineral density, bone fractures, exacerbation of porphyria, hyperglycemia, and other adverse reactions. Monitor for emergence/worsening of depression, suicidal thoughts/behavior, and/or any unusual changes in mood/behavior. Monitor serum levels when switching from Na^+ salt to free acid form and vice versa.

PATIENT COUNSELING

Instruct to read medication guide and to take ud. Advise of the importance of adhering strictly to the prescribed dosage regimen, and of informing the physician of any clinical condition in which it is not possible to take the drug orally as prescribed (eg, surgery). Counsel about the early toxic signs and symptoms of potential hematologic, dermatologic, hypersensitivity, or hepatic reactions; instruct to immediately contact physician if these develop. Caution on the use of other drugs or alcoholic beverages without first seeking physician's advice. Stress the importance of good dental hygiene to minimize the development of gingival hyperplasia and its complications. Advise to notify physician immediately if depression, suicidal thoughts/behavior, or thoughts about self-harm emerge. Encourage patients to enroll in the North American Antiepileptic Drug Pregnancy Registry.

STORAGE

20-25°C (68-77°F). Protect from moisture. (Cap, ER) Preserve in tight, light-resistant containers. (Sus) Protect from freezing and light.

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