Prednisone Tablets (prednisone) - Drug Summary

Qualitest Pharmaceuticals

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Related Drug Information

Prednisone (prednisone)

COMMON BRAND NAMES

Prednisone Intensol, Prednisone

THERAPEUTIC CLASS

Glucocorticoid

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Steroid-Responsive Disorders

Initial: 5-60mg/day, depending on disease and response
Maint: Decrease initial dose in small decrements to lowest effective dose

Alternate-Day Therapy: Administer twice the usual daily dose every other am; refer to PI for more detailed information

Multiple Sclerosis

Acute Exacerbations:
200mg/day for 1 week, followed by 80mg qod for 1 month

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DOSING CONSIDERATIONS

Elderly
Start at lower end of dosing range

Discontinuation
Withdraw gradually after long-term therapy

ADMINISTRATION

Oral route

Take before, during, or immediately pc or w/ food or milk to reduce gastric irritation
Administer in the am prior to 9 am; when large doses are given, administer antacids between meals
Multiple dose therapy should be evenly distributed in evenly spaced intervals throughout the day

HOW SUPPLIED

Sol: (Intensol) 5mg/mL [30mL]; 5mg/5mL [120mL, 500mL]; Tab: 1mg*, 2.5mg*, 5mg*, 10mg*, 20mg*, 50mg* *scored

CONTRAINDICATIONS

Systemic fungal infections.

WARNINGS/PRECAUTIONS

Monitor for situations that may make dosage adjustments necessary (eg, change in clinical status secondary to remissions/exacerbations in the disease process, individual drug responsiveness, effect of patient exposure to stress). Anaphylactoid reactions may occur. May need to increase dose before, during, and after stressful situation. May cause BP elevation, salt/water retention, and increased K^+ and Ca^{2+} excretion; dietary salt restriction and K^+ supplementation may be necessary. Caution in patients w/ a recent MI. May produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression w/ the potential for corticosteroid insufficiency after withdrawal of treatment. Metabolic clearance is decreased in hypothyroid patients and increased in hyperthyroid patients; changes in thyroid status may necessitate dose adjustment. May increase susceptibility to infections, mask signs of current infection, activate latent disease, or exacerbate intercurrent infections. Avoid use in the presence of systemic fungal infections unless needed to control life-threatening drug reactions. Rule out latent or active amebiasis before initiating therapy. Caution w/ *Strongyloides* infestation, active/latent TB or tuberculin reactivity, HTN, CHF, and renal insufficiency. Caution w/ active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses, and nonspecific ulcerative colitis; may increase risk of perforation. Signs of peritoneal irritation following GI perforation may be minimal/absent. Not for use in cerebral malaria and active ocular herpes simplex. May cause more serious/fatal course of chickenpox and measles; avoid exposure, and if exposed, consider prophylaxis/treatment. May produce posterior subcapsular cataracts, glaucoma w/ possible optic nerve damage, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Kaposi's sarcoma reported. Not recommended in optic neuritis treatment. Drug-induced secondary adrenocortical insufficiency may be minimized by gradual dose reduction. Enhanced effect in patients w/ hypothyroidism and cirrhosis. May decrease bone formation and increase bone resorption, and may lead to inhibition of bone growth in pediatric patients and development of osteoporosis at any age; caution w/ increased risk of osteoporosis. Acute myopathy w/ high doses reported, most often in patients w/ neuromuscular transmission disorders (eg, myasthenia gravis). Psychiatric derangements may appear and existing emotional instability or psychotic tendencies may be aggravated. Elevation of creatine kinase (CK) may occur. May elevate IOP; monitor IOP if used for >6 weeks. May suppress reactions to skin tests.

ADVERSE REACTIONS

Anaphylactoid reactions, HTN, osteoporosis, muscle weakness, menstrual irregularities, insomnia, impaired wound healing, ulcerative esophagitis, increased sweating, decreased carbohydrate tolerance, glaucoma, weight gain, nausea, malaise, anemia.

DRUG INTERACTIONS

Live or live, attenuated vaccines are contraindicated w/ immunosuppressive doses. May diminish response to toxoids and live or inactivated vaccines. Closely monitor for hypokalemia when administered w/ K^+-depleting agents (eg, amphotericin B, diuretics). Cardiac enlargement and CHF may occur w/ concomitant use of amphotericin B. Macrolide antibiotics may decrease clearance. Concomitant use w/ anticholinesterase agents (eg, neostigmine, pyridostigmine) may produce severe weakness in myasthenia gravis patients; d/c anticholinesterase agents at least 24 hrs before start of therapy. May inhibit response to warfarin; frequently monitor coagulation indices. May increase blood glucose levels; dose adjustment of antidiabetic agents may be required. May decrease serum concentration of isoniazid. Extreme caution w/ bupropion; employ low initial dosing and small gradual increases. Cholestyramine may increase clearance. Increased activity of both drugs may occur w/ cyclosporine; convulsions reported w/ concurrent use. May increase risk of arrhythmias due to hypokalemia w/ digitalis glycosides. Estrogens, including oral contraceptives, may decrease hepatic metabolism and increase effect. Increased risk of tendon rupture, especially in elderly, w/ concomitant fluoroquinolones. CYP3A4 inducers (eg, barbiturates, phenytoin, carbamazepine, rifampin) may enhance metabolism and may require increase in corticosteroid dose. CYP3A4 inhibitors (eg, ketoconazole, ritonavir, macrolide antibiotics such as erythromycin) may increase plasma levels. May increase clearance of other drugs that are metabolized by CYP3A4 (eg, indinavir, erythromycin), resulting in decreased plasma levels. Increased risk of corticosteroid side effects w/ ketoconazole. Aspirin (ASA) or other NSAIDs may increase risk of GI side effects. Caution w/ ASA in hypoprothrombinemia patients. May increase clearance of salicylates. Decreased therapeutic effect w/ phenytoin. Increased doses of quetiapine may be required to maintain control of schizophrenia symptoms. Caution w/ thalidomide; toxic epidermal necrolysis reported w/ concomitant use. Acute myopathy reported w/ neuromuscular blocking drugs (eg, pancuronium).

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Glucocorticoid; causes profound and varied metabolic effects and modifies the body's immune responses to diverse stimuli.

PHARMACOKINETICS

Absorption: Readily absorbed (GI tract). **Distribution:** Found in breast milk (systemically administered).

ASSESSMENT

Assess for hypersensitivity to drug, CHF, HTN, renal impairment, systemic fungal infections, other current infections, active TB, latent/active amebiasis, cerebral malaria, active ocular herpes simplex, emotional instability or psychotic tendencies, recent MI, vaccination history, thyroid status, any other conditions where treatment is cautioned, pregnancy/nursing status, and for possible drug interactions.

MONITORING

Monitor for anaphylactoid reactions, HPA axis suppression, adrenocortical insufficiency, salt/water retention, infections, change in thyroid status, cataracts, glaucoma, Kaposi's sarcoma, emotional instability or psychotic

tendencies aggravation, and other adverse reactions. Monitor IOP, BP, CK, and serum electrolytes. Monitor growth and development of infants/children on prolonged therapy. Frequently monitor coagulation indices w/ warfarin.

PATIENT COUNSELING

Instruct not to d/c therapy abruptly or w/o medical supervision. Instruct to inform any medical attendants of intake of corticosteroids and to seek medical advice at once if fever or other signs of infection develop. Advise to avoid exposure to chickenpox or measles; instruct to seek medical advice w/o delay if exposed.

STORAGE

20-25°C (68-77°F). (Tab) Protect from moisture. (Intensol) Discard opened bottle after 90 days.

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