Prednisone

(prednisone)

OTHER BRAND NAMES

Prednisone Intensol

THERAPEUTIC CLASS

Glucocorticoid

DEA CLASS

RX

INDICATIONS

Steroid-responsive disorders.

ADULT DOSAGE

Adults: Individualize dose. Initial: 5-60mg/day, depending on disease being treated. Maintain/adjust initial dose until satisfactory response is noted. If no satisfactory clinical response after a reasonable period, d/c and transfer to other appropriate therapy. Maint: Decrease dose by small amounts to lowest effective dose. Withdraw gradually after long-term therapy. Acute Exacerbations of Multiple Sclerosis (MS): 200mg/day for 1 week followed by 80mg qod for 1 month. Alternate Day Therapy (ADT): Twice the usual daily dose administered every other am. Refer to PI for detailed information for ADT. Elderly: Start at lower end of dosing range.

PEDIATRIC DOSAGE

Pediatrics: Individualize dose. Initial: 5-60mg/day, depending on disease being treated. Maintain/adjust initial dose until satisfactory response is noted. If no satisfactory clinical response after a reasonable period, d/c and transfer to other appropriate therapy. Maint: Decrease dose by small amounts to lowest effective dose. Withdraw gradually after long-term therapy. Acute Exacerbations of MS: 200mg/day for 1 week followed by 80mg qod for 1 month. ADT: Twice the usual daily dose administered every other am. Refer to PI for detailed information for ADT.

ADMINISTRATION

Oral route. Refer to PI for further administration instructions.

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 with left ventricular free wall rupture after a recent myocardial infarction (MI). May produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for corticosteroid insufficiency after withdrawal of treatment. 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 with *Strongyloides* infestation, active/latent tuberculosis (TB) or tuberculin reactivity, HTN, congestive heart failure (CHF), and renal insufficiency. Caution with 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. More serious or fatal course of chickenpox and measles reported. May produce posterior subcapsular cataracts, glaucoma with possible optic nerve damage, and enhance establishment of secondary ocular infections due to bacteria, fungi, or viruses. Kaposi's sarcoma reported. Not recommended in optic neuritis treatment. Avoid abrupt withdrawal. Drug-induced secondary adrenocortical insufficiency may be minimized by gradual dose reduction. Enhanced effect in patients with 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 with increased risk of osteoporosis (eg, postmenopausal women). Acute myopathy with high doses reported, most often in patients with 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 intraocular pressure (IOP); monitor IOP if used for >6 weeks. May suppress reactions to skin tests. Caution in elderly.

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

PATIENT COUNSELING

Instruct not to d/c therapy abruptly or without medical supervision. Instruct to advise 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 report immediately without delay if exposed.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F). (Tab) Protect from moisture. (Intensol) Discard opened bottle after 90 days.