NURTURE MED
Nurturing the Health of Filipino Families

Prednisolone

Neopred

20 mg/5 mL Syrup
20 mg Tablet
5 mg Tablet
CORTICOSTEROID

FORMULATION:
Each 5 mL (1 teaspoonful) contains:
Prednisolone..... 20 mg

Each tablet contains:
Prednisolone..... 20 mg

Each tablet contains:
Prednisolone..... 5 mg

DESCRIPTION:
Prednisolone is a glucocorticoid given, as the free alcohol or in esterified form, orally or parenterally, in the treatment of various disorders in which corticosteroids are indicated, except adrenal deficiency states. Adverse effects are those of corticosteroid in general. It has relatively slight mineralocorticoid effects.

INDICATIONS:
For the condition in which systemic corticosteroid therapy is indicated, except adrenocortical-deficiency states for which hydrocortisone with supplementary fludrocortisones is preferred.

PHARMACOKINETICS:
Prednisolone and prednisone are both readily absorbed from the gastrointestinal tract, whereas prednisolone already exists in metabolically active form, prednisone must be converted in the liver to its active metabolite, prednisolone. In general, this conversion is rapid so that prednisone has a preconversion biological half-life of only about 60 minutes. Hence, although prednisone has been estimated to have only about 80% the bioavailability of prednisolone, this difference is of little consequence when seen in the light of intersubject variation in the pharmacokinetics of prednisolone itself; bioavailability also depends on the dissolution rates of the tablet formulations. Nevertheless, prednisolone is the more reliably absorbed of the two corticosteroids, particularly in some liver diseases where the conversion of prednisone may be diminished.
Peak plasma concentrations of prednisolone are obtained 1 to 2 hours after administration by mouth, and it has a usual plasma half-life of 2 to 4 hours. Its initial absorption, but not its overall bioavailability, is affected by food.
Prednisolone is extensively bound to plasma proteins, although less so than hydrocortisone (cortisol).
Prednisolone is excreted in the urine as free and conjugated metabolites, together with an appreciable proportion of unchanged prednisolone. Prednisolone is largely inactivated as it crosses the placenta; small amounts are excreted in breast milk.
Prednisolone has a biological half-life lasting several hours, intermediate between those of hydrocortisone (cortisol) and the longer-acting glucocorticoids, such as dexamethasone. It is this intermediate duration of action that makes it suitable for the alternate-day dosage regimens which have been found to reduce the risk of adrenocortical insufficiency, yet provide adequate corticosteroid coverage in some disorders.

DOSAGE AND ADMINISTRATION:
The usual dose for prednisolone is 2.5 mg to 60 mg daily in divided doses, as a single daily dose after breakfast, or as a double dose on alternate days. Alternate-day early morning dosage regimens produce less suppression of the hypothalamic-pituitary axis but may not always provide adequate control or as prescribed by the physician.

PRECAUTIONS:
Systemic corticosteroids should be used with great caution in the presence of heart failure, recent myocardial infarction, or hypertension, in patients with diabetes mellitus, epilepsy, glaucoma, hypothyroidism, hepatic failure osteoporosis, peptic ulceration psychoses or severe affective disorders, and renal impairment. Children may be at increased risk of some adverse effects; in addition, corticosteroids may cause growth retardation, and prolonged use is rarely justified. The elderly too may be at greater risk from adverse effects.

CONTRAINDICATIONS:
Corticosteroids are usually contraindicated in the presence of acute infections uncontrolled by appropriate antimicrobial therapy. Similarly, patients already receiving corticosteroids are more susceptible to infection the symptoms of which, moreover, may be masked until an advanced stage has been reached. Patients with active or doubtfully quiescent tuberculosis should not be given corticosteroids except, very rarely, as adjunct to treatment with antitubercular drugs. Patients with quiescent tuberculosis should be observed closely and should receive chemoprophylaxis if corticosteroid therapy is prolonged.
During prolonged courses of corticosteroid therapy, patients should be examined regularly. Sodium intake may need to be reduced and calcium and potassium supplements may be necessary. Monitoring of the fluid intake and output, and daily weight records may give early warning of fluid retention. Back pain may signify osteoporosis.

ADVERSE EFFECTS:
The adverse effects of corticosteroids may result from unwanted mineralocorticoid or glucocorticoid actions, or from inhibition of the hypothalamic-pituitary adrenal axis.
Mineralocorticoid adverse effects are manifested in the retention of sodium and water with edema and hypertension, and in the increased excretion of potassium with the possibility of hypokalemic alkalosis. In susceptible patients, cardiac failure may be induced.
Adverse **glucocorticoid** effects lead to mobilisation of calcium and phosphorus, with osteoporosis and spontaneous fractures; muscle wasting and nitrogen depletion; and hyperglycemia with accentuation or precipitation of the diabetic state. The insulin requirements of diabetic patients are increased. Increased appetite is often reported.
Impaired tissue repair and immune function can lead to delayed wound healing, and increased susceptibility to infection. Increased susceptibility to all kinds of infection, including septicemia, tuberculosis, fungal infections, and viral infections, has been reported in patients on corticosteroid therapy. Infections may also be masked by the anti-inflammatory, analgesic, and antipyretic effects of glucocorticoids. The increased severity of varicella and measles may lead to a fatal outcome in non-immune patients receiving systemic corticosteroid therapy.
Other adverse effects include menstrual irregularities, amenorrhea, hyperhidrosis, skin thinning, ocular changes including development of glaucoma and cataract, mental and neurological disturbances, benign intracranial hypertension, acute pancreatitis, and avascular necrosis of bone. An increase in the coagulability of the blood may lead to thromboembolic complications. Peptic ulceration has been reported but reviews of the literature do not always agree that corticosteroids are responsible for an increased incidence. Adverse effects should be treated symptomatically, with the corticosteroid dosage reduced or slowly withdrawn where possible.

DRUG INTERACTION:
Concurrent use of barbiturates, carbamazepine, phenytoin, primidone, or rifampicin may enhance the metabolism and reduce the effects of systemic prednisolone. Conversely oral contraceptives or ritonavir may increase plasma concentrations of prednisolone. Use of prednisolone with potassium-depleting diuretics, such as thiazides or furosemide, may cause excessive potassium loss. There is also an increased risk of hypokalemia with concurrent amphotericin B or bronchodilator therapy with xanthines or $beta_2$ agonists. There may be an increased incidence of gastrointestinal bleeding and ulceration when prednisolone is given with NSAIDs. Response to anticoagulants may be altered by prednisolone and requirements of antidiabetic drugs and antihypertensives may be increased. Prednisolone may decrease serum concentrations of salicylates and may decrease the effect of anticholinesterases in myasthenia gravis.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY:
Prednisolone 20 mg / 5 mL Syrup
Amber Bottle - Bottle of 30 mL and 60 mL

Prednisolone 5 mg & 20 mg Tablets
Alu/Clear PVDC Blister Pack x 10's (Box of 100's)

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

If you suspect any adverse drug reaction, consult your doctor immediately and e-mail us at customerrelations@dynadrug.com

For suspected adverse drug reaction, report to FDA: www.fda.gov.ph

Manufactured by:
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City of Malolos, Bulacan

Manufactured for:
NURTURE MED
Nurturing the Health of Filipino Families
Captain Henry Javier St. cor. Danny Floro St.,
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FDA Registration Number:
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Neopred 20 mg Tablet - Reg. No.: DR-XY43121
Neopred 20 mg / 5 mL Syrup - Reg. No.: DR-XY43017

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