PREDNISONE

PROLIX™

Tablet/Suspension

CORTICOSTEROID

FORMULATION:

Each tablet contains:
Prednisone ..... 20 mg
Each 5 ml (teaspoonful) contains:
Prednisone ..... 10 mg

PRODUCT DESCRIPTION:

Prednisone is a synthetic corticosteroid that has potent anti-inflammatory and immunosuppressive actions.
Prednisone is used in a wide variety of clinical circumstances and disorders where its immunosuppressive properties may be beneficial.

PHARMACODYNAMICS AND PHARMACOKINETICS:

The actions of prednisone as a strong anti-inflammatory agent account for its numerous beneficial effects in controlling manifestations of a wide range of clinical disorders.

Prednisone delivers broad and potent anti-inflammatory effects through multiple mechanisms. Prednisone inhibits the production of inflammatory substances.

Prednisone has advantage over the other steroids because it exerts little effect on renal reabsorption while possessing very potent anti-inflammatory actions. It has very minimal salt-retaining properties.

Like other corticosteroids, prednisone is metabolized mainly in the liver but is also metabolized in other tissues. Prednisone is readily absorbed from the gastrointestinal tract following oral administration and is rapidly distributed to all body tissues.

In the liver, it is rapidly converted into a more active form, prednisolone, which has greater anti-inflammatory and less salt-retaining actions. Peak plasma concentration is obtained 1 to 2 hours after oral administration.

In the prednisolone form, it has a biological half-life of about 12-36 hours, so dosage may be adjusted to the functional pattern of circadian rhythm to decrease risk of adrenal insufficiency. Prednisone is extensively bound to plasma proteins. It is excreted in the urine as free and conjugated metabolites together with proportion of unchanged prednisolone. Small amounts of prednisolone are excreted in breast milk.

INDICATIONS:

Prednisone is indicated in a wide variety of clinical circumstances or disorders affecting the endocrine, nervous, cardiovascular, renal (e.g., nephrotic syndrome), gastrointestinal, skin and integumentary systems, ocular and respiratory systems of inflammatory and allergic origin (e.g., bronchial asthma and skin allergies).

DOSAGE & ADMINISTRATION:

Dosage may vary depending on the severity of the disorder and the response of the patient.
Prednisone is usually taken at 5-60 mg daily in divided doses or as a single dose after breakfast or as a double dose on alternate days. Some patients may temporarily require higher dose to control the disease. Dosage is reduced gradually or tapered off as soon as symptoms diminish.

As an immunosuppressive agent, the usual dose range for prednisone is 10-100 mg orally, daily.

5-25 mg daily in divided doses may be given for primary and secondary adrenocortical insufficiency.

10-20 mg/m2 body surface may be administered daily in divided doses in adrenogenital syndromes.

PREGNANCY AND LACTATION:

Studies have shown that the use of corticosteroids in pregnancy had no adverse effects on the fetus in terms of psychological development or growth. It was reported that prolonged or repeated high doses increased the risk of intra-uterine growth retardation but this did not seem to be a problem following short term therapy.

Use of prednisone in pregnancy and lactation necessitates the consideration of potential benefits of the drug weighed against the possible risks to the mother and the fetus.

ADVERSE DRUG REACTIONS:

Adverse effects such as adrenal suppression may occur when prednisone is used chronically.

Some adverse reactions include gastrointestinal distress, nausea, peptic ulcer, behavioral disturbances, fluid and electrolyte imbalance, visual disturbances, growth retardation, skin atrophy, moon facie, Cushingoid state, hirsutism and muscle atrophy.

DRUG INTERACTIONS:

The effect of prednisone may be reduced by anticonvulsants, phenobarbital, phenytoin, antihistamines, barbiturates, ephedrine, primidone and rifampicin.

The efficacy of hypoglycemics, diuretics, salicylates and anticholinesterases may be reduced by prednisone.

Prednisone when taken with azathioprine provides salutary effects. Aspirin and estrogen may enhance the effect of prednisone. The dose of prednisone is reduced when taking cyclosporine, an immunosuppressant.

CONTRAINDICATIONS:

Systemic fungal infections, glaucoma, gastric and duodenal ulcers, certain viral infections, acute infections uncontrolled by antibiotic therapy, and severe psychoneuroses.

PRECAUTIONS/WARNINGS:

High doses or chronic therapy with prednisone should be undertaken with great caution in patients with heart disease, hypertension, renal dysfunction, peptic ulcer, systemic fungal infection, history of psychotic disorders, diabetes mellitus, epilepsy, tuberculosis, osteoporosis, glaucoma, hypothyroidism, myasthenia gravis, hepatic failure, diverticulitis, colitis, and viral diseases like herpes.

Patients who receive high dose or those on long term therapy should also be monitored for the following adverse effects: hyperglycemia, glucosuria, sodium retention with edema, hypertension, osteoporosis and fungal infection.

Treatment should not be abruptly stopped. Dosage should be reduced or slowly withdrawn or tapered off to prevent adrenal insufficiency. Treatment regimen should always be under medical supervision. Before therapy is initiated, cardiovascular function and psychological status should be assessed.

OVERDOSE AND TREATMENT:

Prednisone overdose may include symptoms such as fever, muscle or joint pain, nausea, dizziness, fainting, and difficulty of breathing. Prolonged overuse can manifest as moon facie, obesity, unusual hair growth, acne, loss of sexual function and muscle wasting. Large doses of prednisone may produce Cushingoid symptoms typical of adrenal cortex hyperactivity.

Adverse events should be treated symptomatically, with the prednisone dosage reduced or slowly withdrawn or tapered off whenever possible to prevent adrenal insufficiency.

CAUTION:

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

AVAILABILITY:

Tablet: Box of 100's x 20 mg **DR-XY28527**
Suspension: Bottles of 60mL **DR-XY28837**

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of any adverse drug reaction.

Pnsv Asia

Manufactured for:
PNSV ASIA CORP.
4/F S.V. More Group Corporate Center
#16 Scout Tuazon cor. Roces Ave., Quezon City
Metro Manila, Philippines
by: **Lloyd Laboratories, Inc.**
#10 Lloyd Ave., First Bulacan Industrial City
City of Malolos, Bulacan