Methylprednisolone

Prednox

Tablet
Corticosteroid

℞

FORMULATION:
Each tablet contains:
Methylprednisolone ..... 4 mg
Methylprednisolone ..... 16 mg

ACTIONS:
Methylprednisolone, a glucocorticoid, is an adrenocortical steroid which is readily absorbed from the GI Tract.

PRODUCT DESCRIPTION:
Methylprednisolone (Prednox-4)- Caplet, length 10.2 mm and width 5.1mm engraved with "PRD" on one side has an orange color, bitter taste and odorless.
Methylprednisolone (Prednox-16)- Elliptical caplet, with a length of 11.5 mm and width of 6 mm, orange and odorless, one side engraved with "PRD" test and splitting line on the other side.

INDICATIONS:
Suppression of inflammatory and allergic disorders, rheumatic disease, various skin disorders, various blood disorders like hemangioma and the Kasabach-Merritt syndrome, emergency management of acute idiopathic thrombocytopenic purpurra.

DOSAGE:
The initial dosage of Prednox may vary from 4 – 48 mg methylprednisolone/day depending on the specific disease entity being treated.
Children: In general, dosage for children should be based upon clinical response and is at the discretion of the clinician.
Treatment should be limited to the minimum dosage for the shortest period of time. If possible, treatment should be administered as a single dose on alternate days.
Elderly : Treatment of elderly patients, particularly if long-term, should be planned bearing in mind the more serious consequences of the common side effects of corticosteroid in old age, particularly osteoporosis, diabetes, hypertension, susceptibility to infection and thinning of skin.

CONTRAINDICATIONS:
Systemic fungal infections and known hypersensitivity to any of the components of Prednox. Avoid live virus vaccines in those receiving immunosuppressive dose.

WARNINGS:
Corticosteroids may mask some signs of infection and new infections may appear during their use. Prolonged use of corticosteroids may produce posterior sub-capsular cataracts, glaucoma with possible damage to the optic nerves and may enhance the establishment of secondary ocular infections due to fungi or viruses.
Growth may be suppressed in children receiving long-term daily divided dose of glucocorticoid therapy and use of such regimen should be restricted to the most urgent indication. Since there is inadequate evidence of safety in human pregnancy, the use of Prednox in pregnancy, nursing mothers, or women of childbearing potential requires that the benefits of drug be carefully weighed against the potential risk to the mother and embryo or fetus.

ADVERSE REACTIONS:
Fluid and Electrolyte Disturbances, sodium retention, congestive heart failure in susceptible patients, hypertension, fluid retention, potassium loss, and hypokalemic alkalosis

OVERDOSAGE AND TREATMENT:
Treatment of acute overdosage is by supportive and symptomatic therapy For chronic overdosage in the face of severe requiring continuous steroid therapy, the dosage may be reduced only temporarily, or alternate day treatment may be introduced.

PRECAUTIONS:
Corticosteroids should be used with caution in non specific ulcerative colitis if there is a probability of impending perforation, abscess or other pyogenic infection; diverticulitis; fresh intestinal anastomoses; active or latent peptic ulcer, renal insufficiency; hypertension; osteoporosis or myasthenia gravis.

SIDE EFFECTS:
Fluid and Electrolyte Disturbances : Sodium retention.
Congestive heart failure in susceptible patients.
Musculoskeletal : Muscle weakness; steroid myopathy; osteoporosis.
Gastrointestinal : Peptic ulceration with possible perforation and hemorrhage, abdominal distentions.
Dermatologic : Impaired wound healing; thin fragile skin.
Neurological : Increased intracranial pressure; pseudotumor cerebri.
Endocrine : Development of Cushingoid state; suppression of growth in children.
Ophthalmic : Posterior subcapsular cataracts; glaucoma.
Vertigo, menstrual irregularities, decreased carbo tolerance.

SPECIAL PRECAUTIONS:
Stress, hyperthyrodism, cirrhosis, ocular herpes simplex, psychic derangement.

INTERACTIONS:
Convulsions have been reported with concurrent use of methylprednisolone and cyclosporin. Drugs that induce hepatic enzymes, eg. phenobarbital, phenytoin and rifampicin may increase the clearence of methylprednisolone and may require increase in methylprednisolone dose to achieve the desired response.

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

STORAGE:
Store at temperatures not exceeding 30°C.

AVAILABILITY:
Prednox-4 : Aluminum foil strip x 10's (box of 100's), Reg. No. : DRP-5538
Prednox-16 : Aluminum foil strip x 10's (box of 50's), Reg. No. : DRP-5537

ADR Reporting Statement:
For suspected adverse drug reaction, report to the FDA: **www.fda.gov.ph.**
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

Date of First Authorization :	Date of Revision :
DRP-5538- 11 June 2009 DRP-5537- 11 June 2009	11 May 2022

Manufactured by:
PYRIDAM FARMA
PT. PYRIDAM FARMA TBK.
JL. Hanjawar Pacet, Desa Cibodas, Kecamatan Pacet, Cianjur, 43253, Indonesia

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ONE PHARMA
ONE PHARMA MARKETING INC.
L51, B21, Abel Nosce St., BF Resort Village, Talon II, Las Piñas City, Metro Manila

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