

PREDNISONE

ROIDRENAL

5 mg TABLET

Anti-hypertensive

Rx

FORMULATION:

Each Tablet contains:

Prednisone..... 5 mg

DESCRIPTION:

Prednisone is a synthetic, biologically inert corticosteroid which is converted to prednisolone in the liver. It has the same chemical relationship to prednisolone as cortisone has to hydrocortisone.

WHAT IS IN THE MEDICINE?

A white to practically white, odorless, crystalline powder. Slightly soluble in alcohol, in chloroform, in dioxane and in methanol, very slightly soluble in water.

Each Tablet contains 5mg of the active ingredient, Prednisone which is a glucocorticoid. Glucocorticoid are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract.

STRENGTH OF MEDICINE

See Formulation

WHAT IS THIS MEDICINE USED FOR?

For endocrine, rheumatic, hematologic disorders, allergic and edematous states; for collagen, dermatologic, ophthalmic, respiratory and neoplastic diseases.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Initial dose: 1 to 12 tablets (5 to 60mg) daily in divided doses.

Maintenance: 2 to 4 tablets (10 to 20mg) daily in divided doses.

Or as prescribed by the physician.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Patients in prolonged therapy should be checked regularly for hypertension, glycosuria, hypokalemia, gastric discomfort and mental changes. Withdrawal of steroids should be gradual in those prolonged therapy. Use with great caution in patients with peptic ulceration, hypertension, renal or cardiac insufficiency, diabetes mellitus, Cushing's syndrome and in pregnancy.

PHARMACOKINETICS:

Prednisone in humans, the pharmacokinetics is complex. After oral intake, it exhibit rapid absorption and becomes almost completely (80% -100%) available. Peak plasma concentrations reach 1 to 2 hours after oral administration. Distribution of prednisolone is dependent on its protein binding properties.

WHAT OTHER MEDICINES OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Peptic ulcer (unless life - saving), osteoporosis, psychosis active or quiescent, tuberculosis, acute infection and live vaccines.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, just take the next dose and subsequent doses at the usual recommended schedule. Do not double dose.

SIGNS AND SYMPTOMS OF OVERDOSE:

*Altered mental status with agitation (psychosis)
*Burning or itching skin.
*Seizures.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you have taken more than the recommended dosage, consult a doctor or contact a Poison Control Center right away.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperatures not exceeding 30°C.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Tell your doctor if you notice any of the following side effects:

- Vision problems
- Eye pain
- Depression

If you have side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

ADR REPORTING STATEMENT:

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

AVAILABILITY:

PREDNISONE 5 mg Tablet Alu/Clear PVC Blister Pack of 20's (box of 100's)

SHELF-LIFE : 24 Months

Registration No. DR-KY16392

DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION:

26 May 2019

DATE OF REVISION OF PATIENT INFORMATION LEAFLET:

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