**SUMMARY OF PRODUCT CHARACTERISTICS OF PREDNISOLONE 5 MG TABLET**

## 1. Name of the medicinal product

Prednisolone 5 mg tablets

## 2. Qualitative and quantitative composition

Each tablet contains Prednisolone 5mg

Blue, circular, flat bevelled edge tablet plain on both sides.

## 3. Pharmaceutical form

Uncoated tablet.

## 4. Clinical particulars

Prednisolone is a corticosteroid drug with predominant glucocorticoid and low mineralocorticoid activity, making it useful for the treatment of a wide range of inflammatory and auto-immune conditions such as asthma, uveitis, pyoderma gangrenosum, rheumatoid arthritis, ulcerative colitis, temporal arteritis and Crohn's disease, Bell's palsy, multiple sclerosis, cluster headaches, vasculitis, acute lymphoblastic leukemia and autoimmune hepatitis, systemic lupus erythematosus, Kawasaki disease and dermatomyositis. It is also used for treatment of sarcoidosis, though the mechanism is unknown. Prednisolone acetate used to reduce swelling, redness, itching, and allergic reactions affecting the eye. Prednisolone can also be used as an immunosuppressive drug for organ transplants and in cases of adrenal insufficiency (Addison's disease).

### 4.2 Posology and method of administration

Usual Adult Dose for Multiple Sclerosis:

Oral: 5 to 60 mg per day in divided doses 1 to 4 times/day.

Usual Pediatric Dose for Asthma -- Acute:

Oral: 1 to 2 mg/kg/day in divided doses 1 to 2 times a day for 3 to 5 days.

Usual Pediatric Dose for Nephrotic Syndrome:

First 3 episodes: Initial dose: 2 mg/kg/day (maximum dose 80 mg/day) until urine is free of protein for 3 consecutive days (maximum: 28 days); followed by 1 to 1.5 mg/kg/dose every other day for 4 weeks.

Frequent relapses or long-term maintenance dose: 0.5 to 1 mg/kg/dose given every other day for 3 to 6 months.

Usual Pediatric Dose for Bronchopulmonary Dysplasia:

2 mg/kg/day orally divided twice daily for 5 days, followed by 1 mg/kg/day once daily for 3 days, followed by 1 mg/kg/dose every other day for 3 doses.

**4.3 Contraindications**

Live vaccines; herpes simplex keratitis, systemic infection

**4.4 Special warnings and precautions for use**

Patients/carers should be encouraged to seek medical advice if worrying psychological symptoms develop, especially if depressed mood or suicidal ideation is suspected. Patients/carers should also be alert to possible psychiatric disturbances that may occur either during or immediately after dose tapering/withdrawal of systemic steroids, although such reactions have been reported infrequently.

Particular care is required when considering the use of systemic corticosteroids in patients with existing or previous history of severe affective disorders in themselves or in their first degree relatives. These would include depressive or manic-depressive illness and previous steroid psychosis.

Caution is necessary when corticosteroids, including prednisolone, are prescribed to patients with the following conditions and frequent patient monitoring is necessary:

• Diabetes mellitus or in those with a family history of diabetes.

• Glaucoma or in those with a family history of glaucoma.

• Hypertension or congestive heart failure.

• Liver failure.

• Epilepsy.

• Osteoporosis: This is of special importance in post-menopausal females who are at particular risk.

• Patients with a history of severe affective disorders and particularly those with a previous history of corticosteroid induced psychoses.

• Peptic ulceration.

• Previous steroid myopathy.

• Glucocorticoids should be used cautiously in patients with myasthenia gravis receiving anticholinesterase therapy.

• Because cortisone has been reported rarely to increase blood coagulability and to precipitate intravascular thrombosis, thromboembolism, and thrombophlebitis, corticosteroids should be used with caution in patients with thromboembolic disorders.

• Renal insufficiency.

**Withdrawal**

In patients who have received more than physiological doses of systemic corticosteroids (approximately 7.5mg prednisolone or equivalent) for greater than 3 weeks, withdrawal should not be abrupt. How dose reduction should be carried out depends largely on whether the disease is likely to relapse as the dose of systemic corticosteroids is reduced. Clinical assessment of disease activity may be needed during withdrawal. If the disease is unlikely to relapse on withdrawal of systemic corticosteroids but there is uncertainty about HPA suppression, the dose of systemic corticosteroid may be reduced rapidly to physiological doses. Once a daily dose equivalent to 7.5mg of prednisolone is reached, dose reduction should be slower to allow the HPA-axis to recover.

Abrupt withdrawal of systemic corticosteroid treatment, which has continued up to 3 weeks is appropriate if it is considered that the disease is unlikely to relapse. Abrupt withdrawal of doses of up to 40mg daily of prednisolone, or equivalent for 3 weeks is unlikely to lead to clinically relevant HPA-axis suppression, in the majority of patients.

In the following patient groups, gradual withdrawal of systemic corticosteroid therapy should be considered even after courses lasting 3 weeks or less:

• Patients who have had repeated courses of systemic corticosteroids, particularly if taken for greater than 3 weeks,

• When a short course has been prescribed within one year of cessation of long-term therapy (months or years),

• Patients who may have reasons for adrenocortical insufficiency other than exogenous corticosteroid therapy,

• Patients receiving doses of systemic corticosteroid greater than 40mg daily of prednisolone,

• Patients repeatedly taking doses in the evening.

**4.5 Interaction with other medicinal products and other forms of interaction**

Increased requirement of insulin and oral hypoglycaemic. Actions blunted by barbiturates, phenytoin, rifampicin. Increased bioavailability with estrogens and oral contraceptives. Increases plasma salicylate levels. Increased risk of convulsions when used with ciclosporin, increased clearance by carbimazole or carbamazepine. Increased risk of GI bleeding and ulceration when used with NSAIDs. May decrease methotrexate clearance.

**4.6 Fertility, pregnancy and lactation**

It should not give to pregnant women because the drug is secreted in breast milk.

**4.7 Effects on ability to drive and use machines**

There is no evidence to suggest that prednisolone has any affect on the ability to drive or use machines

**4.8 Undesirable effects**

The side effects of Prednisolone are given following:

- Problems with your vision;
- Swelling, rapid weight gain, feeling short of breath;
- Severe depression, unusual thoughts or behavior, seizure (convulsions);
- Bloody or tarry stools, coughing up blood;
- Pancreatitis (severe pain in your upper stomach spreading to your back, nausea and vomiting, fast heart rate);
- Low potassium (confusion, uneven heart rate, extreme thirst, increased urination, leg d is comfort, muscle weakness or limp feeling); or
- Dangerously high blood pressure (severe headache, blurred vision, buzzing in your ears,

anxiety, confusion, chest pain, shortness of breath, uneven heartbeats, seizure).

Less serious side effects may include:

- Sleep problems (insomnia), mood changes;
- Acne, dry skin, thinning skin, bruising or discoloration;
- Slow wound healing;
- Increased sweating;
- Headache, dizziness, spinning sensation;
- Nausea, stomach pain, bloating; or
- Changes in the shape or location of body fat (especially in your arms, legs, face, neck, breasts, and waist).

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs are primarily used for their potent anti-inflammatory effects in disorders of many organ systems. Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

### 5.2 Pharmacokinetic properties

Absorption

Prednisolone is rapidly and apparently almost completely absorbed after oral administration; it reaches peak plasma concentrations after 1-3 hours. There is however wide inter-subject variation suggesting impaired absorption in some individuals. Plasma half-life is about 3 hours in adults and somewhat less in children. Its initial absorption, but not its overall bioavailability, is affected by food. Prednisolone has a biological half-life lasting several hours, making it suitable for alternate-day administration regimens.

Distribution

Prednisolone shows dose dependent pharmacokinetics, with an increase in dose leading to an increase in volume of distribution and plasma clearance. The degree of plasma protein binding

determines the distribution and clearance of free, pharmacologically active drug. Reduced doses are necessary in patients with hypoalbuminaemia.

Biotransformation

Prednisolone is metabolised primarily in the liver to a biologically inactive compound. Liver disease prolongs the half-life of prednisolone and, if the patient has hypoalbuminaemia, also increases the proportion of unbound drug and may thereby increase adverse effects.

Elimination

Prednisolone is excreted in the urine as free and conjugated metabolites, together with small amounts of unchanged prednisolone.

## 6. Pharmaceutical particulars

### 6.1 List of excipients

Maize starch

Lactose

Brilliant blue colorant water soluble

Magnesium stearate

Aerosil

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years

### 6.4 Special precautions for storage

Store in a dry place below 30ºC. Protect from light.

### 6.5 Nature and contents of container

PVC Blister Packing

### 6.6 Special precautions for disposal and other handling

No special requirements for disposal.

## 7. Registrant

Cosmos Limited

## 8. Marketing authorization holder

Cosmos Limited
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