PREDNISAM TABLETS

Prednisolone B.P 5mg

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. NAME OF THE MEDICINAL PRODUCT

PREDNISOLONE B.P. 5mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains 5mg of Prednisolone

Excipients with known effect

Each tablet contains 62mg of lactose

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

Oral Tablet

White circular beveled tablet with 'PREDNISAM' marked on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Prednisolone is used in physiological doses for replacement therapy in adrenal insufficiency and in pharmacological doses for their anti-inflammatory and immunosuppressant glucocorticoid properties.

4.2 Posology and method of administration.

Posology

Adults including the elderly

The lowest effective dose should be used for the minimum period in order to minimise side effects.

The initial dosage may vary from 5mg to 60mg daily in divided doses, as a single dose in the morning after breakfast, or as a double dose on alternate days. Dosage depends on the

disorder being treated. The dose can often be reduced within a few days but may need to be continued for several weeks or months.

2.5 to 15mg daily, but higher doses may be needed. Cushingoid side-effects are more likely above 7.5mg daily.

Special populations

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 corticosteroids in old age.

Children

Although appropriate fractions of the actual dose may be used, dosage will usually be determined by clinical response as in adults. Prednisolone should be used only when specifically indicated, in a minimal dosage and for the shortest possible time

Method of administration

The tablet is an oral administration and should be taken with or after food.

4.3 Contraindications

It is contraindicated in patients with peptic ulcer, osteoporosis, psychoses and in patients with active or doubtfully quiescent tuberculosis.

4.4 Special warnings and precaution for use.

Patients should be warned that potentially severe psychiatric adverse reactions may occur with systemic steroids. Symptoms typically emerge within a few days or weeks of starting the treatment. Risks may be higher with high doses, although dose levels do not allow prediction of the onset, type, severity or duration of reactions. Most reactions recover after either dose reduction or withdrawal, although specific treatment may be necessary.

Patients should be encouraged to seek medical advice if worrying psychological symptoms develop, especially if depressed mood or suicidal ideation is suspected.

Patients should also be alert to possible psychiatric disturbances that may occur either during or immediately after dose tampering/withdrawal of systemic steroids, although such reactions have been reported infrequently.

4.5 Interaction with other medicinal product and other forms of interaction.

The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

The desired effects of hypoglycaemic agents (including insulin), antihypertensives and diuretics are antagonised by corticosteroids; and the hypokalaemic effect of acetazolamide, loop diuretics, thiazide diuretics, carbenoxolone and theophylline are enhanced.

4.6 Pregnancy and Lactation.

Pregnancy

The ability of corticosteroids to cross the placenta varies between individual drugs, however, 88% of prednisolone is inactivated as it crosses the placenta.

There is no evidence that corticosteroids result in an increased incidence of congenital abnormalities, such as cleft palate/lip in man. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids may increase the risk of intra-uterine growth retardation. The use of corticosteroids, including prednisolone, during pregnancy may also result in stillbirth. Hypoadrenalism may, in theory, occur in the neonate following prenatal exposure to corticosteroids but usually resolves spontaneously following birth and is rarely clinically important.

As with all drugs, corticosteroids should only be prescribed when the benefits to the mother and child outweigh the risks. When corticosteroids are essential however, patients with normal pregnancies may be treated as though they were in the non-gravid state.

Lactation

Corticosteroids are excreted in small amounts in breast milk. Corticosteroids distributed into breast milk may suppress growth and interfere with endogenous glucocorticoid production in nursing infants. Since adequate reproductive studies have not been performed in humans with glucocorticoids, these drugs should be administered to nursing mothers only if the benefits of therapy are judged to outweigh the potential risks to the infant.

4.7 Effect on the ability to drive and use machine.

The effect of Prednisolone Tablets on the ability to drive or use machinery has not been evaluated. There is no evidence to suggest that prednisolone may affect these abilities.

4.8 Undesirable effect.

A wide range of psychiatric reactions including affective disorders (such as irritable, euphoric, depressed and labile mood, and suicidal thoughts), psychotic reactions (including mania, delusions, hallucinations, and aggravation of schizophrenia), behavioural disturbances, irritability, anxiety, sleep disturbances, and cognitive dysfunction including confusion and amnesia have been reported. Reactions are common and may occur in both adults and children. In adults, the frequency of severe reactions has been estimated to be 5-6%. Psychological effects have been reported on withdrawal of corticosteroids; the frequency is unknown.

4.9 Overdose.

Reports of acute toxicity and/or death following overdosage of glucocorticoids are rare. No specific antidote is available; treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

Pharmacotherapeutic group: Corticosteroids for systemic use.

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.

Glucortocoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

5.2 Pharmacokinetic properties.

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.

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

Significant differences in the pharmacokinetics of prednisolone amongst menopausal women have been described. The postmenopausal women had reduced unbound clearance, reduced total clearance and increased half-life of prednisolone.

5.3 Preclinical safety data.

Product is not a new chemical entity therefore this section is not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize Starch
Purified Talcum
Magnesium Stearate
Gelatine
Methyl Paraben
Propyl Paraben

6.2 Incompatibilities

Unknown

6.3 Shelf-life

24 Months

6.4 Special precautions for storage

Protect from light and store in a cool dry place below 30^0C

6.5 Nature and composition of immediate packaging

Blister with Transparent PVC/Aluminium foil. Packs of 10 x 10 tablets in a carton

7. MARKETING AUTHORISATION HOLDER

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2, WESTERN RESERVOIR ROAD,
ILORIN,
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8. MARKETING AUTHORISATION NUMBER(S)

04 – 0270.

9. AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 27th April 2021

10. DATE OF REVISION OF THE TEXT

17th August 2025