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Customer Signature & Date

CUSTOMER : IDAMAN PHARMA MANUFACTURING SDN BHD
DESCRIPTION : PREDNISOLONE TABLET 5MG
MEASUREMENT : W:210mm X H:297mm
MATERIAL : SMPO 050

COLOUR : BLACK
FINISHING : FOLD

4.4.2024

pharmaniaga®

IDAMAN PHARMA PREDNISOLONE TABLET 5MG

PRODUCT DESCRIPTION
Clean, dry, round, uniform, flat, bevel edged tablets, scored on one side and white in colour.
Each tablet contains : Prednisolone 5mg.

PHARMACODYNAMICS
Pharmacotherapeutic group: Corticosteroids for systemic use
ATC code: H02AB06
Prednisolone is naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt- retaining properties. It is 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.

PHARMACOKINETICS
Prednisolone is rapidly and almost completely absorbed after oral administration. There is however wide inter-subject variation suggesting impaired absorption in some individuals. Initial absorption of prednisolone is affected by food but not its overall bioavailability. It reaches peak plasma concentration after 1-2 hours of oral administration. Plasma half-life is about 3 hours in adults and somewhat less in children. Prednisolone has a biological half-life lasting several hours, making it suitable for alternative-day administration regimens.

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. Liver disease prolongs the half-life of prednisolone and, if the patient has hypoalbuminaemia, this will also increase the proportion of unbound drug and may thereby increase adverse effects.

Significant differences in the pharmacokinetics of prednisolone amongst menopausal women have been described. Based on published clinical data, the postmenopausal women had reduced unbound clearance (30%), reduced total clearance and increased half-life of prednisolone.

Prednisolone is metabolised primarily in the liver to a biologically inactive compound. It is excreted in the urine as free and conjugated metabolites together with small amounts of unchanged prednisolone.

INDICATIONS
Treatment of allergic disorders - Prednisolone is indicated for the treatment of severe or incapacitating allergic disorders intractable to adequate trials of conventional treatment, such as acute non- infectious laryngeal oedema, bronchial asthma, atopic dermatitis, drug induced hypersensitivity reactions, severe perennial or seasonal allergic rhinitis, serum sickness and urticarial transfusion reactions.
Treatment of collagen disorders - Prednisolone is indicated during an exacerbation or as maintenance therapy in selected cases of acute rheumatic carditis, vasculitis, polymyositis and systemic lupus erythematosus.
Treatment of dermatological disorders - Prednisolone is indicated in the treatment of dermatological disorders, such as bullous dermatitis herpetiformis, exfoliative dermatitis, severe seborrheic dermatitis, severe erythema multiforme, mycosis fungoides, pemphigus and severe psoriasis. Prednisolone is also being used in the treatment of oral lesions associated with some of these conditions. However, the presence of an oral herpetic lesion must be ruled out before initiation of prednisolone therapy.
Treatment of gastrointestinal disorders - Prednisolone is indicated when systemic therapy is required during a critical period of the disease in ulcerative colitis and regional enteritis.
Treatment of desquamative gingivitis - Prednisolone is being used in the treatment of desquamative gingivitis when the diagnosis is confirmed via immunofluorescent biopsy assay.
Treatment of hematologic disorders - Prednisolone is indicated in the treatment of congenital hypoplastic anaemia (erythroid), acquired haemolytic anaemia (autoimmune),erythro-blastopenia (RBC anaemia), secondary thrombocytopenia and idiopathic thrombocytopenic purpura in adults.
Treatment of tuberculous meningitis - Prednisolone is indicated for administration concurrently with appropriate antitubercular chemotherapy in patients with concurrent or impending subarachnoid block.
Treatment of neoplastic disease - Prednisolone is indicated for the palliative management of neoplastic diseases, such as leukemia in adults, acute leukemia in children and lymphomas in adults. Prednisolone is also being used for the same purpose in breast cancer, multiple myeloma and prostate cancer.
Treatment of nephrotic syndrome - Prednisolone is indicated to induce diuresis or remission of proteinuria in idiopathic nephrotic syndrome (without uremia), or caused by lupus erythematosus.
Treatment of Ophthalmic disorders - Prednisolone is indicated in the treatment of severe acute or chronic allergic and inflammatory ophthalmic conditions such as allergic conjunctivitis not controlled topically, chorioretinitis, diffused posterior choroiditis, herpes zoster, ocular inflammation of anterior segment, iridocyclitis, iritis, keratitis, optic neuritis, sympathetic ophthalmia, allergic ulcer of corneal margin not controlled topically and diffused posterior uveitis.
Treatment of respiratory disorders - Prednisolone is indicated in the treatment of respiratory disorders such as berylliosis, noncardiogenic pulmonary oedema (protamine sensitivity induced). Loeffler's syndrome (eosinophilic pneumonitis or hypereosinophilic syndrome), aspiration pneumonitis, sarcoidosis (symptomatic), disseminated or fulminating pulmonary antituberculosis (administered concurrently with appropriate antituberculosis chemotherapy).
Prednisolone is also being used prior to or during extracorporeal circulation in heart surgery if the patient has a pre-existing pulmonary disorder.
Treatment of rheumatic disorders - Prednisolone is indicated as adjunctive therapy during an acute episode or exacerbation of rheumatic disorders, such as ankylosing spondylitis, acute gouty arthritis, psoriatic arthritis, rheumatoid arthritis including juvenile arthritis, acute or subacute bursitis, epicondylitis, post-traumatic osteoarthritis, acute nonspecific tendosynovitis.
Treatment of non-suppurative thyroiditis.
Treatment of hypercalcemia associated with cancer of sarcoidosis.
Treatment of trichinosis with neurological or myocardial involvement.
Treatment of endocrine disorders - Physiological dose of prednisolone is indicated as replacement therapy in chronic primary (Addison's disease) or secondary adrenocortical insufficiency, congenital adrenal hyperplasia and acute adrenocortical insufficiency.
In patients with known or suspected adrenocortical insufficiency, prednisolone is indicated prior to surgery, severe trauma, illness or other stress conditions. In treatment of primary adrenocortical insufficiency prednisolone is usually given concurrently with a mineralocorticoid. Prednisolone is being used for other inflammatory conditions and other non- endocrine diseases responsive to its therapy.
Prophylaxis of organ rejection - Prednisolone is being used for their immunosuppressant effects to reduce the risk of rejection of transplanted organ.

RECOMMENDED DOSAGE
Usual Adult Dose : Oral 5 to 60mg a day as a single dose or in divided doses. Dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient.

Usual Adult Prescribing Limits : Up to 250mg daily.

Usual Paediatric Dose : Adrenal insufficiency - Oral, 140mcg (0.14mg) per kg of body weight or 4mg per square meter of body surface a day in three divided doses.

Other Indications - Oral, 500mcg (0.5mg) to 2mg per kg of body weight or 15 to 60mg per square meter of body surface a day in three divided doses.

Note : The paediatric dosage is determined more by the severity of the condition and response of the patient than by the age or body weight. Inhibition of growth may occur in children taking glucocorticoids in daily doses that are larger than those required for replacement therapy. Alternate-day therapy with an oral intermediate acting glucocorticoid (prednisolone, methyl prednisolone or prednisone and triamcinolone) may decrease growth retardation effects.

ROUTE OF ADMINISTRATION : Oral

CONTRAINDICATIONS
- Systemic infections, unless specific anti-infective therapy is used.
- Hypersensitivity to prednisolone or any of the excipients.
- Ocular herpes simplex because of possible perforation.
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

WARNINGS AND PRECAUTIONS
Undesirable effects may be minimised by using the lowest effective dose for the minimum period and by administering the daily requirement as a single morning dose on alternate days. Frequent patient review is required to titrate the dose appropriately against disease activity.

Patients and/or carers 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/systemic exposure 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/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 systematic steroids, although such reactions have been reported infrequently. Particular care is required when considering the use of systematic 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. Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes and severe depression to frank psychotic manifestations.

Anti-Inflammatory/Immunosuppressive Effects
Suppression of the inflammatory response and immune function increases the susceptibility of infections and their severity. The clinical presentation may often be atypical and serious infections such as septicaemia and tuberculosis may be masked and may reach an advance stage before being recognised. The immunosuppressive effects of glucocorticoids may result in activation of latent infection or exacerbation of intercurrent infections.

Chickenpox: Chickenpox is of particular concern since this normally minor illness may be fatal in immunosuppressed patients. Patients (or parents of children) without a definite history of chickenpox should be advised to avoid close personal contact with chickenpox or herpes zoster and if exposed they should seek urgent medical attention. Passive immunisation with varicella/zoster immunoglobin (VZIG) is needed by exposed non-immune patients who are receiving systemic corticosteroids or who have used them within the previous 3 months; this should be given within 10 days of exposure to chickenpox. If a diagnosis of chickenpox is confirmed, the illness warrants specialist care and urgent treatment. Corticosteroids should not be stopped and the dose may need to be increased.

Measles: Patients should be advised to take particular care to avoid exposure to measles, and to seek immediate medical advice if exposure occurs. Prophylaxis with intramuscular normal immunoglobulin may be needed.

Tuberculosis: Caution is necessary and frequent monitoring required when prescribing corticosteroids for patients with a history of tuberculosis or X-ray changes characteristic of tuberculosis. The emergence of active tuberculosis may, however, be prevented by prophylactic use of anti-tuberculosis therapy

Administration of Live Vaccines: Live vaccines should not be given to individuals on high doses of corticosteroids, due to impaired immune response. Live vaccines should be postponed until at least 3 months after stopping corticosteroid therapy. The antibody response to other vaccines may be diminished.

Tumorigenicity: Direct tumour-inducing effects of the glucocorticoids are not known, but the particular risk that malignancies in patients undergoing immunosuppression with these or other drugs will spread more rapidly is a well-recognised problem.

Adrenocortical Insufficiency
Pharmacologic doses of corticosteroids administered for prolonged periods may result in hypothalamic-pituitary-adrenal (HPA) suppression (secondary adrenocortical insufficiency). The degree and duration of adrenocortical insufficiency produced is variable among patients and depends on the dose, frequency, time of administration and duration of glucocorticoid therapy. In addition, acute adrenal insufficiency leading to a fatal outcome may occur if glucocorticoids are withdrawn abruptly. Drug induced secondary adrenocortical insufficiency may therefore be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently. During prolonged therapy an intercurrent illness, trauma, or surgical procedure will require a temporary increase in dosage; if corticosteroids have been stopped following prolonged therapy they may need to be temporarily re-introduced. Patients should carry "Steroid treatment" cards which give clear guidance on the precautions to be taken to minimise risk and which provide details of prescriber, drug, dosage and the duration of treatment.

Special Precautions
Caution is necessary when oral corticosteroids, including prednisolone tablets, are prescribed in patients with the following conditions and frequent patient monitoring is necessary:
- Osteoporosis; this is of special importance in post-menopausal females, who are particularly at risk
- Menopausal or post-menopausal women: corticosteroid requirements may be reduced.
- Hypertension.
- Congestive heart failure.
- Recent myocardial infarction.
- Existing or previous history of severe affective disorders, especially previous steroid-induced psychoses.
- Emotional instability or psychotic tendencies; these may be aggravated by corticosteroids including prednisolone.
- Cushing's Disease; glucocorticoids can produce or aggravate Cushing's Syndrome.
- Diabetes mellitus or a family history of diabetes.
- Previous history of tuberculosis or X-ray changes characteristic of tuberculosis.
- Glaucoma or a family history of glaucoma.
- Idiopathic central serious chorioretinopathy; glucocorticoid treatment can cause severe exacerbation of bullous exudative retinal detachment and lasting visual loss in some patients.
- Previous steroid-induced myopathy.
- Liver failure.
- Hepatic disease. In patients with acute and active hepatitis, protein binding of glucocorticoids is reduced and peak concentrations of administered glucocorticoids increased; elimination of prednisolone will also be impaired. There is an enhanced effect of corticosteroids in patients with cirrhosis.
- Renal insufficiency.
- Epilepsy and/or seizure disorders.
- Peptic ulceration.
- Hypothyroidism; the effect of corticosteroids may be enhanced.
- Myasthenia gravis; glucocorticoids should be used carefully in patients receiving anticholinesterase therapy.
- Thromboembolic disorders; corticosteroids should be used with caution since cortisone has been reported rarely to increase blood coagulability and to precipitate intravascular thrombosis, thromboembolism and thrombophlebitis.
- Duchene's muscular dystrophy; transient rhabdomyolysis and myoglobinuria may occur following strenuous physical activity. It is not known whether this is due to prednisolone itself or the increased physical activity.
- Pheochromocytoma crisis, which may be fatal, has been reported after administration of systemic corticosteroids. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts and nuclear cataracts (particularly in children), exophthalmos, or increased intraocular pressure, which may result in glaucoma with possible damage to the optic nerves.
Establishment of secondary fungal and viral infections of the eye may also be enhanced in patients receiving glucocorticoids.
Raised intracranial pressure with papilloedema (pseudotumour cerebri) associated with corticosteroid treatment has been reported in both children and adults. The onset usually occurs after treatment withdrawal.

Inflammatory bowel disease: These tablets are not enteric coated. Symptoms recurred in a patient with Crohn's Disease on changing from non-enteric coated to enteric coated tablets of prednisolone. This was not an isolated occurrence in the author's unit, and it was advocated that only non-enteric coated prednisolone tablets should be used in Crohn's disease, and that the enteric coated form should be used with caution in any condition characterised by diarrhoea or a rapid transit.

Use in the 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, especially osteoporosis, diabetes, hypertension, hypokalaemia, susceptibility to infection and thinning of the skin. Close clinical supervision is required to avoid life threatening reactions.

Paediatric population
Corticosteroids cause growth retardation in infancy, childhood and adolescence, which may be irreversible, and therefore long-term administration of pharmacological doses should be avoided. If prolonged therapy is necessary, treatment should be limited to the minimum suppression of the hypothalamo-pituitary adrenal axis and growth retardation. The growth and development of infants and children should be closely monitored. Treatment should be administered where possible as a single dose on alternate days. There is an increased risk of nuclear cataracts.

Scleroderma renal crisis
Caution is required in patients with systemic sclerosis because of an increased incidence of (possibly fatal) scleroderma renal crisis with hypertension and decreased urinary output observed with a daily dose of 15mg or more prednisolone. Blood pressure and renal function (s-creatinine) should therefore be routinely checked. When renal crisis is suspected, blood pressure should be carefully controlled.

INTERACTIONS WITH OTHER MEDICAMENTS

Vaccines	Live vaccines should not be given to individuals with impaired immune responsiveness. The antibody response to other vaccines may be diminished.
Antacids	The absorption of prednisolone may be reduced by large doses of some antacids such as magnesium trisilicate or aluminium hydroxide.
Antibacterials	Rifamycins accelerate metabolism of corticosteroids and thus may reduce their effect. Erythromycin inhibits metabolism of methylprednisolone and possibly other corticosteroids.
Anticholinergics	*Antimuscarinics* Prednisolone has been shown to have antimuscarinic activity. If used in combination with another antimuscarinic drug could cause impairment to memory and attention in the elderly. *Neuromuscular Blocking Agents:* Corticosteroids may antagonise the effects of neuromuscular-blocking agents, such as pancuronium or vecuronium. Careful monitoring is needed when neuromuscular blocking agents are used in patients who have been treated with corticosteroids. An increase in the dose of the neuromuscular blocker may be required.
Anticoagulants	Response to anticoagulants may be reduced or, less often, enhanced by corticosteroids. Close monitoring of the INR or prothrombin time is required to avoid spontaneous bleeding.
Antidiabetic agents	Glucocorticoids may increase blood glucose levels. Patients with diabetes mellitus receiving concurrent insulin and/or oral hypoglycemic agents may require dosage adjustments of such therapy.
Antiepileptics	Carbamazepine, phenobarbital, phenytoin, and primidone accelerate metabolism of corticosteroids and may reduce their effect.

Antifungals	Risk of hypokalaemia may be increased with amphotericin, therefore concomitant use with corticosteroids should be avoided unless corticosteroids are required to control reactions; ketoconazole inhibits metabolism of methylprednisolone and possibly other corticosteroids.
Antithyroids	Prednisolone clearance increased by the use of carbimazole and thiamazole.
Cardiac Glycosides	Increased toxicity if hypokalaemia occurs with corticosteroids.
Ciclosporin	Concomitant administration of prednisolone and ciclosporin may result in decreased plasma clearance of prednisolone (i.e. increased plasma concentration of prednisolone). The need for appropriate dosage adjustment should be considered when these drugs are administered concomitantly.
Cytotoxics	Increased risk of haematological toxicity with methotrexate.
Hepatic microsomal enzyme inducers	Drugs that induce hepatic enzyme cytochrome P-450(CYP) isoenzyme 3A4 such as phenobarbital, phenytoin, rifampicin, rifabutin, carbamazepine, primidone and aminoglutethimide may reduce the therapeutic efficacy of corticosteroids by increasing the rate of metabolism. Lack of expected response may be observed and dosage of prednisolone tablets may need to be increased.
Hepatic microsomal enzyme inhibitors	Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. 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.
Hormonal contraceptives	Oral contraceptives increased prednisolone concentrations by 131%. May increase AUC and reduce clearance in oral contraceptives containing ethinylestradiol, mestranol, desogestrel, levonorgestrel, norgestrel or norethisterone.
Immunosuppressants	Tumorigenicity: direct tumour-inducing effects of the glucocorticoids are not known, but the particular risk that malignancies in patients undergoing immunosuppression with these or other drugs will spread more rapidly is a well-recognised problem.
Liquorice	Glycyrrhizin can delay the clearance of prednisolone.
Mifepristone	Effect of corticosteroids may be reduced for 3-4 days after mifepristone.
Non-steroidal anti-inflammatory drugs	Concomitant administration of ulcerogenic drugs such as indomethacin during corticosteroid therapy may increase the risk of GI ulceration. Aspirin should be used cautiously in conjunction with glucocorticoids in patients with hypoprothrombinaemia. Although concomitant therapy with salicylate and corticosteroids does not appear to increase the incidence or severity of GI ulceration, the possibility of this effect should be considered. Serum salicylate concentrations may decrease when corticosteroids are administered concomitantly. The renal clearance of salicylates is increased by corticosteroids and steroid withdrawal may result in salicylate intoxication. Salicylates and corticosteroids should be used concurrently with caution. Patients receiving both drugs should be observed closely for adverse effects of either drug.
Oestrogens	Oestrogens may potentiate the effects of glucocorticoids and dosage adjustments may be required if oestrogens are added to or withdrawn from a stable dosage regimen.
Protease Inhibitors Antivirals	Ritonavir possibly increases plasma concentrations of prednisolone and other corticosteroids by reduction in clearance of prednisolone through the inhibition of P450 isoenzyme CYP3A4.
Other	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.
Somatropin	Growth promoting effect may be inhibited.
Sympathomimetics	Increased risk of hypokalaemia if high doses of corticosteroids given with high doses of bambuterol, fenoteral, formoterol, ritodrine, salbutamol, salmeterol and terbutaline.

PREGNANCY AND LACTATION

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

Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate, intra-uterine growth retardation affects on brain growth and development. 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. Hypoadrenalism may, in theory, occur in the neonate following prenatal exposure to corticosteroids but usually resolves spontaneously following birth and is rarely clinically important. Cataracts have been observed in infants born to mothers treated with long-term prednisolone during pregnancy. 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. Patients with pre-eclampsia or fluid retention require close monitoring.

Use in 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.

The concentration of the steroid in the milk can be between 5 and 25% of those in the serum and the two roughly parallel one another after an oral dose. There are no reports found regarding neonatal toxicity following exposure to corticosteroids during lactation, however if maternal doses > 40 mg/day of prednisolone is prescribed, the infant should be monitored for adrenal suppression.

SIDE EFFECTS

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.

The incidence of predictable undesirable effects, including hypothalamic-pituitary adrenal suppression correlates with the relative potency of the drug, dosage, timing of administration and the duration of treatment.

System Organ Class	Frequency	Undesirable Effect
Infections and Infestations	Not known	Increases susceptibility to, and severity of infections [1], opportunistic infections, recurrence of dormant tuberculosis, oesophageal candidiasis.
Blood and lymphatic system disorders	Not known	Leucocytosis.
Immune system disorders	Not known	Hypersensitivity including anaphylaxis.
Endocrine disorders	Not known	Suppression of the hypothalamo-pituitary adrenal axis [2], cushingoid facies, impaired carbohydrate tolerance with increased requirement for antidiabetic therapy, manifestation of latent diabetes mellitus.
Metabolism and nutrition disorders	Not known	Sodium and water retention, hypokalaemic alkalosis, potassium loss, negative nitrogen and calcium balance, glucose intolerance and protein catabolism. Increase both high and low density lipoprotein cholesterol concentration in the blood. Increased appetite [3]. Weight gain, obesity, hyperglycaemia, dyslipidaemia.
Psychiatric disorders	Common	Irritability, depressed and labile mood, suicidal thoughts, psychotic reactions, mania, delusions, hallucinations, and aggravation of schizophrenia. behavioural disturbances, irritability, anxiety, sleep disturbances, and cognitive dysfunction including confusion and amnesia.
	Not known	Euphoria, psychological dependence, depression.
Nervous system disorders	Not known	Depression, insomnia, dizziness, headache, vertigo. Raised intracranial pressure with papilloedema (pseudotumor cerebri) [4]. Aggravation of epilepsy, epidural lipomatosis. vertebrobasilar stroke [5].
Eye disorders	Not known	Glaucoma, papilloedema, posterior subcapsular cataracts, nuclear cataracts (particularly in children), exophthalmos, corneal or scleral thinning, exacerbation of ophthalmic viral or fungal disease. Severe exacerbation of bullous exudative retinal detachment; lasting visual loss in some patients with idiopathic central serous chorioretinopathy.
Ear and labyrinth disorders	Not known	Vertigo
Cardiac disorders	Not known	Congestive heart failure in susceptible patients, hypertension, increased risk of heart failure. Increased risk of cardiovascular disease, including myocardial infarction [6]. Bradycardia*
Vascular disorders	Not known	Thromboembolism
Gastrointestinal disorders	Not known	Dyspepsia, nausea, peptic ulceration with perforation and haemorrhage, abdominal distension, abdominal pain, diarrhoea, oesophageal ulceration, acute pancreatitis.
Skin and subcutaneous tissue disorders	Not known	Hirsutism, skin atrophy, bruising, striae, telangiectasia, acne, increased sweating, pruritis, rash, urticaria.
Musculoskeletal and connective tissue disorders	Not known	Proximal myopathy, osteoporosis, vertebral and long bone fractures, avascular osteonecrosis, tendon rupture, tendinopathies (particularly of the Achilles and patellar tendons), myalgia, growth suppression in infancy, childhood and adolescence.
Renal and urinary disorders	Not known	Scleroderma renal crisis*
Reproductive system and breast disorders	Not known	Menstrual irregularity, amenorrhoea.
General disorders and administration site conditions	Not known	Fatigue, malaise, impaired healing.
Investigations	Not known	Increased intra-ocular pressure, may suppress reactions to skin tests.

1. with suppression of clinical symptoms and signs.
2. particularly in times of stress, as in trauma, surgery or illness.
3. which may result in weight gain
4. usually after treatment withdrawal
5. exacerbation of giant cell arteritis, with clinical signs of evolving stroke has been attributed to prednisolone.
6. with high dose therapy

* Following high dose

Withdrawal symptoms

Too rapid a reduction of corticosteroid dosage following prolonged treatment can lead to acute adrenal insufficiency, hypotension and death. A steroid "withdrawal syndrome" seemingly unrelated to adrenocortical insufficiency may also occur following abrupt discontinuance of glucocorticoids. This syndrome includes symptoms such as: anorexia, nausea, vomiting, lethargy, headache, fever, joint pain, desquamation, myalgia, arthralgia, rhinitis, conjunctivitis, painful itchy skin nodules weight loss, and/or hypotension. These effects are thought to be due to the sudden change in glucocorticoid concentration rather than to low corticosteroid levels. Psychological effects have been reported on withdrawal of corticosteroids.

***Description of selected adverse reactions**

Scleroderma renal crisis

Amongst the different subpopulations the occurrence of scleroderma renal crisis varies. The highest risk has been reported in patients with diffuse systemic sclerosis. The lowest risk has been reported in patients with limited systemic sclerosis (2%) and juvenile onset systemic sclerosis (1%).

SYMPTOMS AND TREATMENT OF OVERDOSE

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

High systemic doses of corticosteroids caused by chronic use have been associated with adverse effects such as neuropsychiatric disorders (psychosis, depression, hallucinations), cardiac dysrhythmias and Cushing's syndrome.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

The effect of Idaman Pharma Prednisolone Tablet 5mg on the ability to drive or use machinery has not been evaluated. There is no evidence to suggest that prednisolone may affect these abilities.

INSTRUCTIONS FOR USE

Should be taken with food and with a drink of water.

STORAGE CONDITIONS

Store below 30°C in a cool dry place; Protect from light and moisture.

SHELF LIFE : Product should not be used beyond the expiry date imprinted on the product packaging.

PACK SIZE : Blister Pack of 10's
100 Strips of 10 Tablets

REGISTRATION NO. : MAL19860163AZ

CONTROLLED MEDICINE
UBAT TERKAWAL

KEEP MEDICINE OUT OF REACH OF CHILDREN
JAUHI UBAT-UBATAN DARI KANAK-KANAK

For further information, please consult your doctor or your pharmacist.

Revision Number : 07
Revision Date : 4 April 2024

Lt-119.07 Product Registration Holder and Manufacturer

IDAMAN PHARMA MANUFACTURING SDN BHD (200401023395)
LOT 24 & 25, JALAN PERUSAHAAN LAPAN,BAKAR ARANG
INDUSTRIAL ESTATE, 08000 SUNGAI PETANI,
KEDAH DARUL AMAN, MALAYSIA