

1.3

Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

PREDILIN (Prednisolone Tablets BP 5 mg)

2. Qualitative and quantitative composition

Each uncoated tablet contains:

Prednisolone BP.....5.0 mg

Excipients.....Q.S.

3. Pharmaceutical form

Uncoated tablet

White coloured, circular biconvex, uncoated tablets having embossed “P” breakline “5” on one side & other side plain on each tablet.

4. Clinical particulars

4.1 Therapeutic indications

Prednisolone is indicated in the management of all conditions deemed likely to benefit from short or long term glucocorticoid therapy. These include:

Allergic states

Severe, incapacitating allergies unresponsive to conventional treatment; asthma serum sickness; drug hypersensitivity reactions.

Collagen disorders

Eg systemic lupus erythematosus, polymyositis, polymyalgia rheumatica and temporal (giant cell) arteritis, mixed connective tissue disease syndrome, acute rheumatic carditis.

Rheumatic disorders

Usually given as an adjunctive therapy for short term administration during an acute episode or exacerbation of rheumatoid arthritis, psoriatic arthritis.

Skin conditions

Life-threatening or incapacitating skin conditions such as pemphigus and exfoliative dermatitis.

Neoplastic disease

Leukaemias and lymphomas in adults, acute leukaemia of childhood.

Gastro-Intestinal disease

During acute exacerbation in ulcerative colitis and regional ileitis (Crohn's Disease).

Respiratory disease

Sarcoidosis (especially with hypercalcaemia), fulminating or disseminated pulmonary

tuberculosis when used concurrently with appropriate antituberculosis chemotherapy.

Haematological disorders

Various blood dyscrasias eg selected cases of haemolytic anaemia, thrombocytopenic purpura.

Miscellaneous

Nephrotic syndrome.

4.2 Posology and method of administration

Posology

Adults

20-40 mg daily (acute conditions up to 80 mg daily) reducing gradually to maintenance level when symptoms have subsided. Maintenance dosage is usually 5-20 mg daily reached in about two weeks by reduction of the daily dosage by 5 mg or 2.5 mg, two or three times a week.

Paediatric population

Although appropriate fractions of the actual dose may be used, dosage will usually be determined by clinical response as in adults (see also section Special warnings and precautions for use). Alternate day dosage is preferable where possible.

Corticosteroids cause growth retardation in infancy, childhood and adolescence which may be irreversible. Treatment should be limited to the minimum dosage for the shortest possible time. In order to minimise suppression of the hypothalamo-pituitary adrenal axis and growth retardation, treatment should be administered where possible as a single dose on alternate days.

Elderly

Treatment of elderly patients, especially if long-term, should be planned bearing in mind the more serious consequences of the common side-effects of corticosteroids in old age, particularly diabetes, hypertension, hypokalaemia, osteoporosis, susceptibility to infection and thinning of the skin. Close clinical supervision is required to avoid life-threatening reactions.

The daily dose should be taken in the morning after breakfast. For further information with reference to dosage see warnings and precautions section.

The following therapeutic guidelines should be kept in mind for all therapy with corticosteroids:

Corticosteroids are palliative symptomatic treatment by virtue of their anti-inflammatory effects; they are never curative.

The appropriate individual dose must be determined by trial and error and must be re-evaluated

regularly according to activity of the disease.

As corticosteroid therapy becomes prolonged and as the dose is increased, the incidence of disabling side-effects increases.

In general, initial dosage shall be maintained or adjusted until the anticipated response is observed. The dose should be gradually reduced until the lowest dose which will maintain an adequate clinical response is reached. Use of the lowest effective dose may also minimise side-effects (see 'Special warnings and special precautions for use').

In patients who have received more than physiological dose for systemic corticosteroids (approximately 7.5 mg 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 hypothalamic-pituitary-adrenal (HPA) suppression, the dose of corticosteroid may be reduced rapidly to physiological doses. Once a daily dose equivalent to 7.5 mg 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 40 mg 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 40 mg daily of prednisolone (or equivalent).
- patients repeatedly taking doses in the evening. (See section Special warnings and precautions for use and Undesirable Effects)

During prolonged therapy, dosage may need to be temporarily increased during periods of stress or during exacerbations of the disease (see section Special warnings and precautions for use) If there is lack of a satisfactory clinical response to Prednisolone Tablets, the drug should be gradually discontinued and the patient transferred to alternative therapy.

Intermittent dosage regimen A single dose of Prednisolone Tablets in the morning on alternate days or at longer intervals is acceptable therapy for some patients. When this regimen is practical, the degree of pituitary-adrenal suppression can be minimised.

Specific dosage guidelines The following recommendations for some corticosteroid-responsive disorders are for guidance only. Acute or severe disease may require initial high dose therapy with reduction to the lowest effective maintenance dose as soon as possible. Dosage reductions should not exceed 5-7.5 mg daily during chronic treatment.

Allergic and skin disorders Initial doses of 5-15 mg daily are commonly adequate.

Collagenosis Initial doses of 20-30 mg daily are frequently effective. Those with more severe symptoms may require higher doses.

Rheumatoid arthritis The usual initial dose is 10-15 mg daily. The lowest daily maintenance dose compatible with tolerable symptomatic relief is recommended.

Blood disorders and lymphoma An initial daily dose of 15-60 mg is often necessary with reduction after an adequate clinical or haematological response. Higher doses may be necessary to induce remission in acute leukaemia.

Method of administration: Oral

The daily dose should be taken in the morning after breakfast. For further information with reference to dosage see section Special warnings and precautions for use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section List of excipients.

Systemic infections unless specific anti-infective therapy is employed.

Patients with ocular herpes simplex due to the possibility of perforation.

4.4 Special warnings and precautions for use

A patient information leaflet should be supplied with this product. Patients should carry “steroid treatment” cards which give clear guidance on the precautions to be taken to minimise risk and provide details of prescriber, drug, dosage and duration of treatment.

Patients/and or carers should be warned that potentially severe psychiatric adverse reactions may occur with systemic steroids (see section Undesirable Effects). Symptoms typically

emerge within a few days or weeks of starting the treatment. Risks may be higher with high doses/systemic exposure (see also section pharmacokinetic interactions that can increase the risk of side effects), 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 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.
- Tuberculosis: Those with a history of, or X-ray changes characteristic of tuberculosis. The

emergence of active tuberculosis can, however, be prevented by the prophylactic use of antituberculous therapy.

- Recent myocardial infarction (rupture).
- 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 immunoglobulin (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 special care and urgent treatment.

Corticosteroids should not be stopped and the dose may need to be increased.

- Measles: Patients are advised to avoid exposure to measles, medical advice should be sought if exposure occurs. Prophylaxis with intramuscular normal immunoglobulin may be needed.
- Suppression of the inflammatory response and immune function increases the susceptibility to 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 advanced stage before being recognised.
- The effect of corticosteroids may be enhanced in patients with hypothyroidism in those with chronic liver disease with impaired hepatic function.
- Live vaccines should not be given to individuals with impaired immune responsiveness. The antibody response to other vaccines may be diminished.
- Adrenal cortical atrophy develops during prolonged therapy and may persist for years after stopping treatment.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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 15 mg 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.

Withdrawal

In patients who have received more than physiological doses of systemic corticosteroids (approximately 7.5 mg 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 7.5 mg 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 40 mg 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.

During prolonged therapy any 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 reintroduced.

Use in children:

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.

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.

Excipients

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

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.

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: Drugs that inhibit hepatic enzyme cytochrome P-450 (CYP) isoenzyme 3A4 (e.g. ketoconazole, troleandomycin) may decrease glucocorticoid clearance. Dosages of glucocorticoids given in combination with such drugs may need to be decreased to avoid potential adverse effects.

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.

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.

Antibacterials: Rifamycins accelerate metabolism of corticosteroids and thus may reduce their effect. Erythromycin inhibits metabolism of methylprednisolone and possibly other corticosteroids.

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.

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.

Antivirals: Ritonavir possibly increases plasma concentrations of prednisolone and other corticosteroids.

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.

Mifepristone: Effect of corticosteroids may be reduced for 3-4 days after mifepristone.

Vaccines: Live vaccines should not be given to individuals with impaired immune responsiveness.

The antibody response to other vaccines may be diminished.

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.

Somatropin: Growth promoting effect may be inhibited.

Sympathomimetics: Increased risk of hypokalaemia if high doses of corticosteroids given with high doses of bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline.

Antacids can reduce the absorption of prednisolone if given in high doses. Indigestion remedies should not be taken at the same time of day as Prednisolone.

Corticosteroids should not be used concurrently with retinoids and tetracyclines due to increased intracranial pressure.

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.

4.6 Fertility, 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. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate, intra-uterine growth retardation and 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 intrauterine growth retardation. Hypoadrenalism may occur in the neonate following prenatal exposure to corticosteroids but usually resolves spontaneously following birth and is rarely clinically important. Cataracts have also been rarely reported. 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 abnormal pregnancies may be treated as though they were in the non-gravid state.

Patients with pre-eclampsia or fluid retention require close monitoring.

Lactation

Corticosteroids are excreted in small amounts in breast milk. However doses of up to 40mg daily of prednisolone are unlikely to cause systemic effects in the infant. Infants of mothers taking higher doses than this may have a degree of adrenal suppression but the benefits of breast feeding are likely to out-weigh any theoretical risk. Monitoring of the infant for adrenal suppression is advised.

4.7 Effects on ability to drive and use machines

If insufficient sleep occurs, the likelihood of impaired alertness may be increased, patients should make sure they are not affected before driving or operating machinery.

4.8 Undesirable 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 Not known.

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 (see section Special warnings and precautions for use).

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 or whenever possible as a single morning dose on alternative days. Frequent patient review is required to appropriately titrate the dose against disease activity.

System organ class	Frequency	Undesirable effects
Infections and infestations	Not known	Increases susceptibility to and severity of infections with suppression of clinical symptoms and signs, opportunistic infections, recurrence of dormant tuberculosis (see section Special warnings and precautions for use).
Blood and lymphatic system disorders	Not known	Leucocytosis
Immune system disorders	Not known	Hypersensitivity including anaphylaxis, fatigue, malaise
Endocrine disorders	Not known	Cushing syndrome, cushingoid facies, weight gain, impaired carbohydrate tolerance with increased requirement for antidiabetic therapy, manifestation of latent diabetes mellitus, menstrual irregularity and amenorrhoea
Metabolism and nutrition disorders	Not known	Sodium and water retention, hypokalaemic alkalosis, potassium loss, negative nitrogen and

		calcium balance
Psychiatric disorders	Not known	<p>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), marked euphoria leading to dependence; aggravation of epilepsy, behavioural disturbances, irritability, nervousness, anxiety, sleep disturbances, and cognitive dysfunction including confusion and amnesia have been reported.</p> <p>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. Psychological dependence, dizziness, headache, vertigo.</p>
Eye disorders	Not known	<p>Increased intra-ocular pressure, glaucoma, papilloedema, posterior subcapsular cataracts, central serous chorioretinopathy, exophthalmos,</p>
		<p>corneal or scleral thinning, scleral perforation, exacerbation of ophthalmic viral or fungal disease and vision, blurred (see also section Special warnings and precautions for use)</p>
Cardiac disorders	Not known	<p>Congestive heart failure in susceptible patients, hypertension</p>
Vascular disorders	Not known	<p>Thromboembolism</p>
Gastrointestinal disorders	Not known	<p>Dyspepsia, nausea, peptic ulceration with perforation and haemorrhage, abdominal distension, abdominal pain, increased appetite which may result in weight gain, diarrhoea, oesophageal ulceration, oesophageal candidiasis,</p>

		acute pancreatitis, perforation of the small bowel, particularly in patients with inflammatory bowel disease.
Skin and subcutaneous tissue disorders	Not known	Hirsutism, skin atrophy, bruising, impaired healing, striae, telangiectasia, acne, increased sweating, may suppress reactions to skin tests, pruritis, rash, urticaria
Musculoskeletal and connective tissue disorders	Not known	Proximal myopathy, osteoporosis, vertebral and long bone fractures, avascular osteonecrosis, tendon rupture, myalgia, muscle weakness, wasting and loss of muscle mass.
Renal and urinary disorders	Not known	Nocturia, scleroderma renal crisis*
General disorders and administration site conditions	Not known	Impaired healing, withdrawal symptoms**.

***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%)

****Withdrawal symptoms:** Too rapid a reduction of corticosteroid dosage following prolonged treatment can lead to acute adrenal insufficiency, hypotension and death (see section Special warnings and precautions for use and Posology and method of administration). 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.

Additional side effects in children and adolescents

Suppression of the hypothalamo-pituitary adrenal axis particularly in times of stress, as in trauma, surgery or illness, growth suppression in infancy, childhood and adolescence. Raised intracranial pressure with papilloedema (pseudotumor cerebri) in children, usually after treatment withdrawal.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

In the event of an overdosage, supportive and symptomatic therapy is indicated. Serum electrolytes should be monitored.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids for systematic use, plain

ATC code: H02A B06

Mechanism of action

Prednisolone is one of the highly potent glucocorticoid steroids having anti-inflammatory, hormonal and metabolic effects qualitatively similar to those of hydrocortisone.

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 readily and almost completely absorbed from the GI tract after oral administration.

Distribution

Peak plasma concentrations are obtained 1-2 hours after oral administration. Prednisolone is extensively bound to plasma proteins, although less so than hydrocortisone. Prednisolone crosses the placenta and small amounts are excreted in breast milk.

Biotransformation

Prednisolone is mainly metabolised in the liver and has a usual plasma half-life of 2-3 hours. It has a biological half-life lasting several hours which makes it suitable for the alternate-day administration regimens which have been found to reduce the risk of adrenocortical insufficiency, yet provide adequate corticosteroid coverage in some disorders.

Its initial absorption, but not its overall bioavailability, is affected by food, hepatic or renal impairment and certain drugs.

Elimination

It is excreted in the urine as free and conjugated metabolites, together with an appreciable

proportion of unchanged prednisolone.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose, Maize Starch, Methyl Paraben, Propyl Paraben, Purified Water, Purified Talc, Magnesium Stearate, Colloidal Silicon Dioxide, Croscarmellose Sodium & Sodium Starch Glycolate.

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years from the date of manufacture.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Special precautions for disposal and other handling

No special requirements for disposal

6.6 Nature and contents of container

PREDILIN is a white coloured, circular biconvex, uncoated tablets having embossed “P” breakline “5” on one side & other side plain on each tablet, packed in printed aluminium foil and Clear PVC foil blister containing 10 tablets.

7. Marketing authorisation holder

GENEITH PHARM LTD.

12 Adewale Crescent, Off Ewenla Street,
Off, Oshodi, Apapa, Lagos,
Nigeria.

8. Marketing authorisation number(s)

BD/26 18/04/2023

9. Date of first authorisation/renewal of the authorisation

18/04/2023

Module 1- Administrative & Prescribing Information
Product Name: PREDILIN (Prednisolone Tablets BP 5 mg)

Dosage Form & Label Claim: Tablets
Each uncoated tablet contains:
Prednisolone BP 5 mg
Excipients Q.S.

10. Date of revision of the text

17/03/2028