PREDNISOLONE 5 MG TABLETS BP

PL 06453/0055

UKPAR

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PREDNISOLONE 5 MG TABLETS BP

PL 06453/0055

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency granted Athlone Laboratories Limited a Marketing Authorisation (licence) for the medicinal product Prednisolone 5mg Tablets BP on 18 July 2006. This product is available with a prescription only.

Synthetic corticosteroids similar to this product have been available in the European Union, including the UK, for more than 10 years. Their use is well established with recognised efficacy and acceptable safety.

Prednisolone 5mg Tablets BP raised no clinically significant safety concerns and it was therefore judged that the benefits of using this product outweigh the risks; hence a Marketing Authorisation has been granted.

PREDNISOLONE 5 MG TABLETS BP

PL 06453/0055

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy the UK granted a marketing authorisation for the medicinal product Prednisolone 5mg Tablets BP (PL 06453/0055) to Athlone Laboratories Limited. This product is a POM.

This national application for Prednisolone 5mg Tablets BP is submitted under EC, Article 10c of Directive 2001/83/EC.

Prednisolone tablets contain the active ingredient prednisolon, a glucocorticoid that reduces inflammation. Prednisolone tablets are, therefore, indicated in a variety of diseases that cause inflammation; such as bronchial asthma or rheumatoid arthritis (for a fuller list see Summary of Product Characteristics on page 10 of this report).

PHARMACEUTICAL ASSESSMENT

INTRODUCTION

This is an abridged application made under Article 10c of EC Directive 2001/83 and is considered to be an identical product to that of Prednisolone Tablets 5mg (PL 08215/0006) licensed to Kent Pharmaceuticals Limited. A letter authorising Athlone to cross-refer to this licence is provided. The proposed holder of this Marketing Authorisation has access to all the data supporting this application.

EXPERT REPORT

Expert statements in relation to the pharmaceutical, preclinical and clinical aspects of this product confirming that it is identical to the cross-reference product have been provided from suitably qualified persons.

PRODUCT NAME

The name of the product is Prednisolone 5mg Tablets BP.

MARKETING AUTHORISATION APPLICATION (MAA)

The MAA submitted is satisfactory.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

The SPC is in line with the cross-reference product and is satisfactory.

LABELLING

All labelling is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The Patient Information Leaflet is in line with the SPC and the requirements of Directive 2001/83/EC and is satisfactory.

RECOMMENDATION

A grant of a Marketing Authorisation is acceptable.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application is consistent with that previously assessed for the cross-reference product and, as such, have been judged to be satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type.

EFFICACY
No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with those of the cross-reference products.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The risk benefit ratio is considered to be positive.

PREDNISOLONE 5 MG TABLETS BP

PL 06453/0055

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application on 27 June 2003
2	Following assessment of the application, the MHRA requested further information relating to the quality dossier on 30 October 2003
3	The applicant responded to the MHRA's requests, providing further information on 15 December 2004
4	Following assessment of the applicant's response, the MHRA requested further information relating to the quality dossier on 3 March 2005
5	The applicant responded to the MHRA's requests, providing further information on 29 September 2005
6	Following assessment of the applicant's response, the MHRA requested further information relating to the quality dossier on 24 November 2005
7	The applicant responded to the MHRA's requests, providing further information on 26 April 2006
8	Following assessment of the applicant's response, the MHRA requested further information relating to the quality dossier on 22 May 2006
9	The applicant responded to the MHRA's requests, providing further information on 16 June 2006
10	The application was determined on 18 July 2006

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Prednisolone 5mg Tablets BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5mg of prednisolone.
For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Tablet.
White, round tablets scored on one side

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prednisolone is a glucocorticoid, which is four times as active as hydrocortisone on a weight for weight basis.

A wide variety of diseases may sometimes require glucocorticoid therapy. Some of the principle indications are;
Bronchial asthma, severe hypersensitivity reactions, anaphylaxis;
Rheumatoid arthritis, systemic lupus erythematosus, dermatomyositis, mixed connective tissue disease (excluding systemic sclerosis), polyarteritis nodosa;

Inflammatory skin disorders, including pemphigus vulgaris, bullous pemphigoid and pyoderma gangrenosum;
Minimal change nephrotic syndrome, acute interstitial nephritis;

Ulcerative colitis, Crohn's disease; sarcoidosis; rheumatic carditis;
haemolytic anaemia (auto-immune), acute and lymphatic leukaemia, malignant lymphoma, multiple myeloma, idiopathic thrombocytopenic purpura; immunosuppression in transplantation.

4.2 Posology and method of administration

For oral use

The lowest dose to produce an acceptable result should be given; when it is possible to reduce the dose this must be by stages. In prolonged treatment, the dose may be increased temporarily during periods of stress or exacerbation of illness.

The dose will depend on the disease, its severity, and the clinical response. The doses below are for guidance only.

The daily dose should be taken in divided doses or as a single daily dose at 8am or as a double dose on alternate days. When a regimen of taking a single dose in the morning on alternate days or at longer intervals is practical for the patient's therapy the degree of pituitary-adrenal suppression can be minimised.

Adults:
Short term treatment: 20 to 30mg daily for the first few days, reducing by 2.5 to 5mg every 2 to 5 days according to the response.

Rheumatoid arthritis: Initially 7.5 to 10mg daily reduced to the lowest effective dose for maintenance.

Most other conditions: 10 to 100mg daily for 1 to 3 weeks, then reducing to the lowest effective dose.

Elderly:

There is no evidence that the dosage should differ; the dose should be the minimum necessary to achieve the desired therapeutic effect.

Children:
At 12 years, 75% of the adult dose; at 7 years, 50% of the adult dose; at 1 year 25% of the adult dose dependent on clinical factors. Initial dose 0.75 to 1.0mg/kg of bodyweight daily, in divided doses.

When long term treatment is to be discontinued, the dose administered should be gradually reduced over a period of weeks or months depending on dosage and duration of therapy.

(Refer to Prednisolone Withdrawal under section 4.4)

4.3 Contraindications

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

Systemic infections, unless specific anti - infective therapy is employed; live virus immunisation; hypersensitivity to any component of the tablets.

Ocular herpes simplex because of possible perforation.

4.4 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 on alternate days. Frequent

patient review is required to titrate the dose appropriately against disease activity.

Adrenal suppression: Adrenal cortical atrophy develops during prolonged therapy and may persist for years after stopping treatment. Withdrawal of corticosteroids after prolonged therapy must therefore always be gradual to avoid acute adrenal insufficiency, being tapered off over weeks or months according to the dose and duration of treatment (see below). 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 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 the prescriber, drug, dosage and the duration of treatment

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 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.

Cushing's disease: Because glucocorticoids can produce or aggravate *Cushing's syndrome*, glucocorticoids should be avoided in patients with Cushing's disease.

Caution is necessary when prescribing corticosteroids in the following conditions and frequent patient monitoring is required:

a) Previous history of tuberculosis or characteristic appearance on chest X-ray.
The emergence of active tuberculosis can, however, be prevented by the prophylactic use of antituberculous therapy.

b) Diabetes mellitus (or a family history of diabetes).

c) Osteoporosis (post menopausal females are particularly at risk).

d) Hypertension.

e) History of severe affective disorders (especially previous history of steroid psychosis).

f) Glaucoma (or a family history of glaucoma).

g) Previous steroid myopathy.

h) Peptic ulceration.

i) Epilepsy.

j) Vaccination with live vaccines. Live vaccines should be postponed until at least 3 months after stopping corticosteroid therapy.

k) Congestive heart failure.

l) Liver failure.

m) Renal insufficiency.

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

o) 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.

The effect of corticosteroids may be enhanced in patients with hypothyroidism and in those with chronic liver disease with impaired hepatic function.

During treatment the patient should be observed for psychotic reactions and muscle weakness, electrocardiographic changes, hypertension and untoward hormonal effects.

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 infection such as septicaemia and tuberculosis may be masked and may reach an advanced stage before being recognised.

Killed vaccine or toxoids may be given though their effects may be attenuated.

Use in Children

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

Use in the Elderly
Treatment of the 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.

Prednisolone 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 corticosteroids 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 corticosteroids 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 patients groups, gradual withdrawal of systemic corticosteroids 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 (or equivalent).

- Patients repeatedly taking doses in the evening.

4.5 Interaction with other medicinal products and other forms of interaction

Hepatic microsomal enzyme inducers: Drugs that can cause liver enzyme induction 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 the dose of prednisolone may need to be increased.

Non-steroidal anti-inflammatory drugs: Concomitant administration of ulcerogenic drugs such as indometacin 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.

Cytotoxins: 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 (see section 4.4).

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.

Others: The desired effects of hypoglycaemia 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.
Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate, intra-uterine growth retardation and effects 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. 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. 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 outweigh any theoretical risk.

4.7 Effects on ability to drive and use machines

No or negligible effect

4.8 Undesirable effects

The following side effects may be associated with the long-term systemic use of corticosteroids:

Gastro-intestinal: Dyspepsia, peptic ulceration with perforation and haemorrhage, abdominal distension, oesophageal ulceration, oesophageal candidiasis, acute pancreatitis.

Musculoskeletal: Proximal myopathy, osteoporosis, vertebral and long bone fracture, avascular osteonecrosis, tendon rupture.
Fluid and electrolyte disturbance: Sodium and water retention, hypertension and hypokalemic alkalosis.

Dermatological: Impaired healing, skin atrophy, bruising, striae, acne and telangiectasia.

Endocrine / Metabolic: Suppression of the hypothalamo-pituitary adrenal axis growth suppression in childhood and adolescence, menstrual irregularity and amenorrhoea. Cushingoid facies, hirsutism, weight gain, impaired carbohydrate tolerance with increased requirement for antidiabetic therapy; negative nitrogen and calcium balance. Increased appetite.
Neuropsychiatric: Euphoria, psychological dependence, depression, insomnia. Raised intracranial pressure with papilloedema (pseudotumor cerebri) in children, usually after treatment withdrawal. Aggravation of schizophrenia. Aggravation of epilepsy.

Ophthalmic: Increased intra-ocular pressure, glaucoma, papilloedema, posterior subcapsular cataracts, corneal or scleral thinning, exacerbation of ophthalmic viral disease.

General: Opportunistic infection, recurrence of dormant tuberculosis, leucocytosis, hypersensitivity, thromboembolism, increased appetite, nausea and malaise.

Withdrawal Symptoms: Too rapid a reduction of corticosteroid dosage following prolonged treatment can lead to acute adrenal insufficiency, hypotension and death (see section 4.4). A "withdrawal syndrome" may also occur including; fever, myalgia, arthralgia, rhinitis, conjunctivitis, painful itchy skin nodules and loss of weight.
Prednisolone has a biological half-life lasting several hours, it is this duration of action which makes it suitable for the alternative day regimen, which has been found to reduce the risk of adrenocortical insufficiency, yet provide adequate corticosteroid coverage in some disorders.

4.9 Overdose

Treatment is symptomatic but is unlikely to be required

PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: HO2A B06

Prednisolone is a glucocorticoid with the general properties of corticosteroids. It is used for its anti-inflammatory and immuno-suppressant properties, which suppress the clinical manifestations of disease in a wide range of disorders.

Naturally occurring glucocorticoids play an important role in homeostatis, stressful situations stimulate their release and they enable the body to resist noxious stimuli and environmental changes. They exert important effects on gluconeogenesis and the proper functioning of many tissues and organ systems.

Most of the actions of glucocorticoids have been shown to be exerted in the nuclei of the target tissue. They enter the cell and combine with specific steroid-binding receptor proteins. The complex enters the nucleus and interacts with the chromatin materials, allowing synthesis of appropriate enzymes. Since the actions of the glucocorticoids depend on protein synthesis, they can be blocked in the body by drugs that inhibit protein synthesis.

5.2 Pharmacokinetic properties

Prednisolone is absorbed from the gastro-intestinal tract, peak plasma concentrations of prednisolone are obtained 1 to 2 hours after administration by mouth, and it has a usual plasma half-life of 2-4 hours. Its initial absorption, but not its overall bioavailability is affected by food.

Prednisolone is extensively bound to plasma proteins, although less so than hydrocortisone.

Prednisolone is excreted unchanged in the urine as free and conjugated metabolites, together with an appreciable proportion of unchanged prednisolone. Prednisolone crosses the placenta and small amounts are excreted in breast milk.

Prednisolone has a biological half-life lasting several hours, it is this duration of action which makes it suitable for the alternative day regimen, which has been found to reduce the risk of adrenocortical insufficiency, yet provide adequate corticosteroid coverage in some disorders.

5.3 Preclinical safety data

Prednisolone is a drug that has been available for a number of years and consequently a wide range of toxicological studies have been undertaken in both man and animals.

Reproductive studies in animals have shown development of abnormalities and effects on fertility. Effects have been observed at oral doses of 1200mg/kg in mice and 250mg/kg in rats.

In women, prednisolone has been shown to cause developmental effects at doses 23mg/kg.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package. Keep the bottle tightly closed.

6.5 Nature and contents of container

Securitainers - polypropylene homopolymer containers with either low density polyethylene caps or LDPE/HDPE mixture caps.

Available in pack sizes of 28, 30, 500 and 1000.

6.6 Special precautions for disposal

Standard precautions for the handling of corticosteroids must be observed

7 MARKETING AUTHORISATION HOLDER

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

PL 06453/0055

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/07/2006

10 DATE OF REVISION OF THE TEXT

18/07/2006

PATIENT INFORMATION LEAFLET

Patient Information Leaflet

PREDNISOLONE 5mg TABLETS BP

Please read this leaflet carefully before you start to take your medicine. However this leaflet does not tell you everything about your medicine. So, if you have any questions or are not sure about anything, ask your doctor or pharmacist.

DESCRIPTION OF TABLETS:

Prednisolone 5mg Tablets BP are white, round tablets scored on one side, each containing 5mg of prednisolone BP. The tablets also contain lactose monohydrate, maize starch and magnesium stearate.

WHAT SORT OF MEDICINE IS PREDNISOLONE BP ?

Prednisolone BP is a glucocorticoid, which has anti-inflammatory and anti-allergy properties. It is one of a group of corticosteroid or "steroid" medicines, which have anti-inflammatory and immuno-suppressant properties. They reduce the symptoms of a wide range of diseases by reducing the inflammation (or reaction), caused by the disease. (They should not be confused with "anabolic" steroids misused by bodybuilders). Prednisolone 5mg Tablets BP are available in packs of 28, 30, 500 and 1000. Prednisolone 5mg Tablets BP are only available on prescription from your doctor.
The marketing authorisation holder & company responsible for release of this medicine to market is Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland. The product licence number is PL 06453/0055.
Distributed by: Kent Pharmaceuticals Ltd., Wotton Road, Ashford, Kent, TN23 6LL, U.K.

HOW DOES YOUR MEDICINE WORK ?

Prednisolone BP is a glucocorticoid. The body has naturally occurring glucocorticoids, which are chemical messengers, and play an important role in controlling the body's systems e.g. temperature control. In stressful situations such as change of temperature or injury to the body they are released to control the situation. Glucocorticoids can affect every cell in the body, and prednisolone BP acts on individual cells to reduce the reaction to inflammation, therefore reducing the swelling and the feeling of pain. Many different diseases may be improved by the careful use of glucocorticoids like prednisolone BP, by its actions at cell level. They are mainly conditions where the body has had an inflammatory reaction to some event and prednisolone BP reduces this reaction. For example in arthritis there is an inflammation of the joints and taking prednisolone BP reduces this reaction. If you are not sure why you are on these tablets, ask your doctor.

BEFORE TAKING THESE TABLETS....

If you answer YES to any of the following questions, or are not sure, talk to your doctor or pharmacist before taking Prednisolone 5mg Tablets BP.
" Are you suffering from an untreated infection?
" Are you suffering from a herpes infection of the eye?
" Have you recently had a vaccination?
" Have you ever had a reaction to prednisolone BP or any other 'steroids'?
" Have you ever had a reaction to any of the ingredients in the tablets (as listed above)?
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

ADVICE ON TAKING YOUR MEDICINE

If you can answer YES to the following questions do not use Prednisolone 5mg Tablets BP until you have informed your doctor:
" Are you planning a family, or if you think you might be pregnant or are breast-feeding?
" Have you ever had an infection called tuberculosis (TB)?
" Are you diabetic (sugar in urine) or is anybody in your family?
" Has your doctor told you that you have brittle bones?
" Do you have high blood pressure?
" Have you ever had treatment for mental illness?
" Do you have glaucoma (high pressure in the eyes) or has anyone in your family?
" Have you taken steroids before and suffered from muscle weakness?
" Do you suffer from stomach ulcers?
" Are you epileptic?
" Do you suffer from any problems with your heart?
" Do you suffer from liver disease?
" Do you suffer from kidney disease?
" Do you suffer from thyroid disease?
" Do you have any problems with your blood clotting?
" Do you suffer from myasthenia gravis?
" Do you suffer from Cushing's disease?
Your doctor will prescribe the lowest dose for the shortest possible time to relieve your symptoms. When it is time to reduce the amount of tablets you take, this reduction will be carried out gradually over a period of weeks or months depending on how many tablets you are taking. It is important to follow your doctor's instructions exactly when reducing the dose of Prednisolone 5mg Tablets BP. Live vaccines should be postponed until at least 3 months after stopping corticosteroid therapy. In treatment over a longer period of time, the dose may be increased temporarily during periods of stress (e.g. after surgery) or if your illness becomes temporarily worse. If it is necessary for you to take Prednisolone 5mg Tablets BP for a long period of time, your doctor will review your condition regularly. You should carry a steroid treatment card, which will give information about the dose of Prednisolone 5mg Tablets BP you are taking; how long you have been taking it; why you need it, and who prescribed it for you. Taking prednisolone BP will reduce your body's ability to make natural glucocorticoid and this may cause slowing of normal growth in children. The amount of medicine taken should therefore be limited to the smallest dosage for the shortest possible time. To reduce this effect, Prednisolone 5mg Tablets BP should be taken as a single morning dose on every other day, if possible. Ask your doctor about this if you (or your child) will be taking Prednisolone 5mg Tablets BP.
It is important to be aware that contracting chickenpox whilst taking these tablets, and for a period afterwards, can be dangerous. You must immediately contact your doctor if you come into contact with someone who has chickenpox or measles during treatment with Prednisolone 5mg Tablets BP, and for up to three months after stopping the tablets.
You may start to feel better after taking these tablets for a few days but do not stop taking them unless your doctor has told you. If you require more information about taking Prednisolone 5mg Tablets BP, talk to your doctor or pharmacist.

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TAKING OTHER MEDICINES WITH PREDNISOLONE 5mg TABLETS BP

If you take other medicines as well as Prednisolone 5mg Tablets BP, it may effect how they work in your body. If you are taking any of the following medicines make sure that your doctor is aware of this:
* Anti-cholinesterase inhibitors (tablets that increase your muscle control)
* Phenytoin, phenobarbitone, primidone and carbamazepine (medicine to control fits and seizures)
* Rifampicin (antibiotic medicine)
* Ephedrine (a cold remedy, to dry up a runny nose)
* Anticoagulants (blood thinning tablets, e.g. warfarin)
* Oral hypoglycaemics (tablets for diabetes)
* Loop diuretics, thiazides (water tablets) and carbenoxolone (for stomach ulcers)
* Theophylline (anti-asthma)
* Non-steroidal anti-inflammatory drugs (e.g. Indometacin, Ibuprofen)
* Aspirins
* Ketoconazole, amphotericin (antifungal medicines)
* Ritonavir (antiviral medicine)
* Digoxin (a medicine used for the treatment of heart disease)
* Ciclosporin (immune suppressing medicine used in organ transplants)
* Methotrexate (a medicine used for the treatment of cancer and other conditions)
* Mifepristone (an abortion inducing medicine)
* Vaccines
* Oestrogens (female hormones)
* Somatropin (human growth hormone)
* Bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline (drugs to treat asthma)

HOW TO TAKE YOUR TABLETS ?

Your doctor has carefully chosen the correct dosage for you taking into account the severity of your condition, your age and any other particular reasons special to you, therefore you should always take the dose prescribed.
Check the pharmacist's label on your medicine, it should tell you how many tablets to take and when to take them. If it does not or you are not sure ask your doctor.
Your doctor will have calculated the lowest needed dosage to relieve your condition and will give instructions on when to reduce the original dose and at what rate. Where treatment is prolonged your doctor may give you specific instructions on how to increase the dose temporarily during periods of stress or if the illness becomes worse.
All doses of Prednisolone 5mg Tablets BP can be taken spread throughout the day, or as a single dose at the start of your day, or as a double dose on alternate days. For oral use.
Adults:
Short-term treatment: 4 to 6 tablets per day for the first few days, reducing by ½ or 1 tablet every 2 to 5 days according to the response. Rheumatoid arthritis: Initially, 1½ or 2 tablets daily reduced to the lowest effective dose.
Other Conditions: 2 to 20 tablets daily for 1 to 3 weeks, then reducing to the lowest effective dose.
The Elderly:
There is no evidence that the dosage should differ; the dose should be the minimum necessary to achieve the desired therapeutic effect.
Children:
* At 12 years: 75% of the adult dose
* At 7 years: 50% of the adult dose
* At 1 year: 25% of the adult dose

The dosage and number of the tablets to be taken will be calculated by your doctor. If someone else has swallowed any of your tablets, tell a doctor immediately and contact your nearest hospital casualty department. If you forget to take a dose take a dose as soon as you remember.

ARE THERE ANY SIDE EFFECTS TO THIS MEDICINE ?

Along with its needed effects a medicine may cause unwanted effects. Most people taking this medicine find it causes them no problems. Occasionally, some patients may have an upset stomach or a skin rash. Treatment over a long period of time, may lead to problems with the eyes (cataracts or glaucoma), high blood pressure, bone thinning and thinning of the skin and stretch marks. Children taking doses over a long period of time may experience a reduction in growth. Taking these tablets can make it easier for you to pick up infections and mild infections can be made worse.
Other possible side effects include: upset stomach, indigestion, stomach ulcers, pancreatitis (severe stomach pain), ulcers or fungal infection (thrush) of the oesophagus, muscle weakness, water retention, poor skin healing, acne, irregularity of periods, increased appetite and growth of body hair, depression, worsening of schizophrenia and epilepsy and increased risk of blood clots. **It is important not to suddenly stop taking Prednisolone 5mg Tablets BP as this may cause side-effects so make sure that you do not run out of these tablets.** Your doctor will take this into account when recommending Prednisolone 5mg Tablets BP and will make regular checks on your health if you need to take this medicine over a long period of time. Too rapid a reduction of this medicine following prolonged treatment can lead to hormone insufficiency, low blood pressure and even death.
A "withdrawal syndrome" may also occur including; fever, muscle pain, joint pain, inflammation of the eyes and nasal passages, itchy skin lumps and weight loss. If you take too much Prednisolone 5mg Tablets BP or you feel unwell after taking them, please tell your doctor immediately or contact your nearest hospital casualty department.

STORING YOUR TABLETS

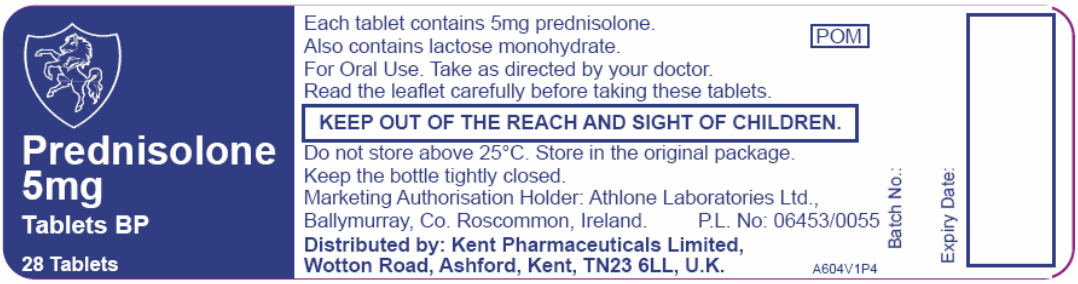
Do not use the medicine after the expiry date, which is on the container your medicine came in. If the expiry date has passed, take the medicine back to the pharmacist.
* **KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.**
* Do not store above 25°C. Store in the original package. Keep the bottle tighly closed.

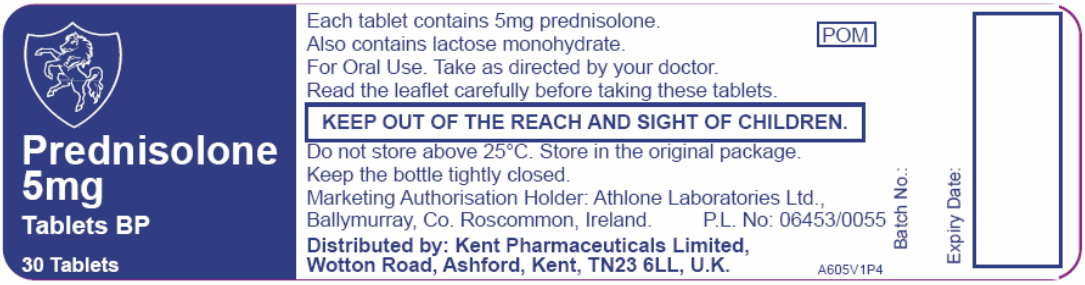
If your doctor decides to stop treatment, return any leftover tablets to your pharmacist. Only keep them if your doctor tells you to. Please keep this leaflet safe while you are taking this medicine, as you may need to read it again.

PL 06453/0055
Date of Preparation: September 2005

A608V1P8

LABELLING


Prednisolone 5mg
Tablets BP
28 Tablets
Each tablet contains 5mg prednisolone.
Also contains lactose monohydrate.
For Oral Use. Take as directed by your doctor.
Read the leaflet carefully before taking these tablets.
POM
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
Do not store above 25°C. Store in the original package.
Keep the bottle tightly closed.
Marketing Authorisation Holder: Athlone Laboratories Ltd.,
Ballymurray, Co. Roscommon, Ireland. P.L. No: 06453/0055
Distributed by: Kent Pharmaceuticals Limited,
Wotton Road, Ashford, Kent, TN23 6LL, U.K.
A604V1P4
Batch No.:
Expiry Date:


Prednisolone 5mg
Tablets BP
30 Tablets
Each tablet contains 5mg prednisolone.
Also contains lactose monohydrate.
For Oral Use. Take as directed by your doctor.
Read the leaflet carefully before taking these tablets.
POM
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
Do not store above 25°C. Store in the original package.
Keep the bottle tightly closed.
Marketing Authorisation Holder: Athlone Laboratories Ltd.,
Ballymurray, Co. Roscommon, Ireland. P.L. No: 06453/0055
Distributed by: Kent Pharmaceuticals Limited,
Wotton Road, Ashford, Kent, TN23 6LL, U.K.
A605V1P4
Batch No.:
Expiry Date:


Prednisolone 5mg
Tablets BP
500 Tablets
Each tablet contains 5mg prednisolone.
Also contains lactose monohydrate.
For Oral Use. Take as directed by your doctor.
Read the leaflet carefully before taking these tablets.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
Do not store above 25°C.
POM
Store in the original package.
Keep the bottle tightly closed.
Marketing Authorisation Holder:
Athlone Laboratories Ltd., Ballymurray,
Co. Roscommon, Ireland.
P.L. No: 06453/0055
Distributed by: Kent Pharmaceuticals Limited,
Wotton Road, Ashford, Kent, TN23 6LL, U.K.
A606V1P3
Batch No.:
Expiry Date:


Prednisolone
5mg
Tablets BP
1000 Tablets
Each tablet contains 5mg prednisolone.
Also contains lactose monohydrate.
For Oral Use. Take as directed by your doctor.
Read the leaflet carefully before taking these tablets.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
Do not store above 25°C.
Store in the original package.
Keep the bottle tightly closed.
POM
Marketing Authorisation Holder:
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