GLOBAL PRESCRIBER INFORMATION

TITLE

Betamethasone

SCOPE

Trade Name(s)

BETNELAN ™ Tablets.

Formulation, Strength and Device* (*if appropriate)

Tablets.

Excipients

Lactose, Maize starch, Gelatin, Magnesium stearate.

CLINICAL INFORMATION

Indications

A wide variety of diseases may sometimes require corticosteroid therapy. Some of the principal 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 (autoimmune).

- Acute and lymphoblastic and chronic lymphocytic leukaemia - malignant lymphoma.
- Multiple myeloma.
- Idiopathic thrombocytopenic purpura.
- Immunosuppression in transplantation.

Dosage and Administration

The lowest dosage that will produce an acceptable result should be used. When it is possible to reduce the dosage, this must be accomplished in stages. During prolonged therapy, dosage may need to be increased temporarily during periods of stress or in exacerbations of illness.

Populations

- **Adults**

The dose used will depend upon the disease, its severity, and the clinical response obtained. The following regimens are for guidance only. Divided dosage is usually employed.

Short-term treatment: 2 to 3 mg daily for the first few days, subsequently reducing the daily dosage by 250 or 500 micrograms (0.25 or 0.5 mg) every two to five days, depending upon the response.

Rheumatoid arthritis: 500 micrograms (0.5 mg) to 2 mg daily. For maintenance therapy the lowest effective dosage is used.

Most other conditions: 1.5 to 5 mg daily for one to three weeks, then reducing to the minimum effective dosage. Larger doses may be needed for mixed connective tissue diseases and ulcerative colitis.

- **Children**

Fractions of the adult dosage may be used (e.g. 75% at 12 years, 50% at 7 years and 25% at 1 year) but clinical factors must be given due weight.

Contraindications

- Systemic infections, unless specific anti-infective therapy is employed.

- Live virus immunisation.

- Hypersensitivity to any component of the tablets.

Warnings and Precautions

Administration of corticosteroids may impair the ability to resist and counteract infection e.g. where there is a previous history of tuberculosis; in addition clinical signs and symptoms of infection are suppressed.

Chickenpox is of particular concern since this normally minor illness may be fatal in immunosuppressed patients. Patients without a definite history of chickenpox should be advised to avoid close contact with chickenpox or herpes zoster and, if exposed, they (or the parents of such children) should see 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 three months. This should be given within ten 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.

Corticosteroid treatment is likely to reduce the response of the pituitary-adrenal axis to stress, and relative insufficiency may persist for up to a year after withdrawal of prolonged therapy.

Because of the possibility of fluid retention, care must be taken when corticosteroids are administered to patients with congestive heart failure.

Corticosteroids may worsen diabetes mellitus, osteoporosis, hypertension, glaucoma and epilepsy.

Care should be taken when there is a history of severe affective disorders (especially a previous history of steroid psychosis), previous steroid myopathy or peptic ulceration.

In patients with liver failure blood levels of corticosteroid may be increased, as with other drugs which are metabolised in the liver.

Systemic corticosteroids may 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 HPA axis and growth retardation consideration should be given to administration of a single dose on alternate days.

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, susceptibility to infection and thinning of the skin.

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

In rare cases reduction or withdrawal of oral corticosteroid therapy may unmask underlying eosinophilic conditions (e.g. Churg Strauss syndrome) in patients with asthma.

Interactions

Corticosteroids may reduce the effects of anticholinesterases in myasthenia gravis, cholecystographic x-ray media, salicylates and non-steroidal anti-inflammatory agents.

The effect of corticosteroids may be reduced by phenytoin, phenobarbitone, ephedrine and rifampicin.

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.

The dosage of concomitantly administered anti-coagulants may have to be altered (usually decreased).

Pregnancy and Lactation

The use of corticosteroids during human pregnancy and lactation requires that the benefits be weighed against the possible risks associated with the product or with any alternative therapy.

Fertility

No Text.

Pregnancy

There is insufficient evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. The relevance of this finding to human beings has not been established, however, patients should avoid extensive use in pregnancy.

Hypoadrenalism may occur in the neonate.

Lactation

Corticosteroids are excreted in small amounts in breast milk and infants of mothers taking pharmacological doses of steroids should be monitored carefully for signs of adrenal suppression.

Ability to perform tasks that require judgement, motor or cognitive skills

No Text.

Adverse Reactions

Prolonged treatment with corticosteroids in high dosage is occasionally associated with subcapsular cataract, skin thinning, osteoporosis, and glaucoma. In addition, any of the features of hypercortisolism, such as suppression of the HPA axis, may occur.

Aseptic osteonecrosis, particularly of the femoral head, may occur after prolonged corticosteroid therapy or after repeated short courses involving high dosage.

Peptic ulceration may develop, or be aggravated.

In children, prolonged therapy may retard growth.

In patients on long term therapy fluid and electrolyte balance may be altered.

Other rare side effects that have been reported include benign intracranial hypertension and pyschic instability.

Clinical Trial Data

No Text.

Postmarketing Data

No Text.

Overdosage

Acute overdosage is very unlikely to occur, however in the case of chronic overdosage or misuse the features of hypercortisolism, may appear and in this situation the product should be discontinued slowly.

Symptoms and Signs

No Text.

Treatment

No Text.

Clinical Pharmacology

Pharmacodynamics

ATC Code

No Text.

Mechanism of Action

No Text.

Pharmacodynamic Effects

No Text.

Pharmacokinetics

No Text.

Absorption

No Text.

Distribution

No Text.

Metabolism

No Text.

Elimination

No Text.

Special Patient Populations

No Text.

Clinical Studies

No Text.

NON-CLINICAL INFORMATION

No Text.

PHARMACEUTICAL INFORMATION

Chemical Structure

No Text.

Shelf-Life

No Text.

Storage

Protect from light.

Store below 30°C.

Nature and Contents of Container

No Text.

Incompatibilities

No Text.

Use and Handling

No Text.

REFERENCES

No Text.

GLOBAL PATIENT LEAFLET

TITLE

No Text.

SCOPE

No Text.

Trade Name(s) of the product

No Text.

Formulation, strength and device * (*if appropriate)

No Text.

Excipients requiring special warnings

No Text.

WHAT “TRADE NAME” IS AND WHAT IT IS USED FOR

No Text.

BEFORE YOU TAKE/USE “TRADE NAME”

No Text.

HOW TO USE “TRADE NAME”

No Text.

ONCE YOU HAVE STARTED USING “TRADE NAME”

No Text.

POSSIBLE SIDE EFFECTS

No Text.

STORING “TRADE NAME”

No Text.

GLOBAL PACKAGING COMPONENTS

TITLE

No Text.

BETNELAN is a trademark of the GlaxoSmithKline group of companies.