Betason®

Corticosteroid
Tablets

Composition
Each tablet contains:
Active ingredient: Betamethasone 0.5mg.
Excipients: Maize starch, lactose monohydrate and magnesium stearate.

Properties
Betason® is a potent synthetic glucocorticoid which acts mainly as an anti-inflammatory and immunosuppressant.
As an anti-inflammatory, it decreases or prevents tissue responses to inflammatory processes, thereby reducing development of symptoms of inflammation without affecting the underlying cause.
Mechanism of immunosuppressant action is not completely understood but may involve prevention of suppression of cell-mediated (delayed hypersensitivity) immune reactions as well as more specific actions affecting the immune response.
Following oral administration, Betason® reaches its peak effect within 1 - 2 hours. It is highly protein bounded, with a plasma half-life of 3 - 5 hours.

Indications
Betason® is indicated in:
- Acute episode or exacerbation of rheumatic disorders such as rheumatoid arthritis, juvenile arthritis, post-traumatic osteoarthritis, synovitis of osteoarthritis, ankylosing spondylitis, psoriatic arthritis, acute gouty arthritis, acute calcium pyrophosphate deposition disease, and rheumatic fever.
- Acute episode or exacerbation of nonrheumatic disorders such as an acute or subacute bursitis, epicondylitis, and acute nonspecific tenosynovitis.
- Collagen diseases such as mixed connective tissue disease (excluding systemic sclerosis), acute rheumatic carditis, polymyositis, polyarteritis nodosa, relapsing polychondritis, vasculitis, and systemic lupus erythematosus.
- Allergic diseases such as severe hay fever, serum sickness, urticaria, angioedema, bee stings and drug-induced reactions.
- Dermatological diseases such as pemphigus, severe erythema multiforme, atopic dermatitis, contact dermatitis, exfoliative dermatitis, bullous herpetiformis dermatitis, severe seborrheic dermatitis, severe inflammatory dermatoses, mycosis fungoides, severe psoriasis, severe eczema, localized cutaneous sarcoid, and nonsuppurative thyroiditis.
- Treatment of oral lesions, which are unresponsive to topical therapy such as desquamative gingivitis, postoperative dental inflammatory reactions, oral lesions associated with corticosteroid-responsive disorders, recurrent aphthous stomatitis, nasal polyps, and pericarditis to relieve fever and inflammation.
- Respiratory disorders such as bronchial asthma, berylliosis, Loeffler’s syndrome, aspiration pneumonitis, symptomatic sarcoidosis, disseminated or fulminating pulmonary tuberculosis (as an adjunct), acute or chronic asthmatic bronchitis, pulmonary emphysema, idiopathic pulmonary fibrosis, and status asthmaticus.
- Severe acute or chronic allergic and inflammatory ophthalmic conditions such as chorioretinitis, diffuse posterior choroiditis, allergic conjunctivitis that is not controlled topically, herpes zoster ophthalmicus, anterior segment inflammation, iridocyclitis, iritis, keratitis that is not associated with herpes simplex or fungal infections, optic neuritis, sympathetic ophthalmia, corneal marginal allergic ulcers, diffuse posterior uveitis, and retrobulbar neuritis.
- Substitution therapy, in primary or secondary adrenocortical insufficiency, congenital adrenal hyperplasia, and sarcoidosis.
- Gastrointestinal disorders such as ulcerative colitis, Crohn’s disease, and refractory sprue.
- Hematologic disorders such as haemolytic anaemia (autoimmune), congenital hypoplastic anaemia, red blood cell anaemia, secondary thrombocytopenia, idiopathic thrombocytopenic purpura, and haemolysis.
- Neoplastic diseases in conjunction with appropriate specific antineoplastic disease therapy for palliative management. This includes acute or chronic lymphocytic anaemia, Hodgkin’s or non-Hodgkin’s lymphomas, breast carcinoma, prostatic carcinoma, multiple myeloma, and nephrotic syndrome. It is used as well as an adjunct in primary brain tumors and in fever due to malignancy.
- Neurologic disease such as tuberculous meningitis (as an adjunct treatment) and myasthenia gravis.
- Miscellaneous, such as immunosuppression in transplantation, as well as trichinosis with neurological or myocardial involvement

Dosage

The dose will depend upon the disease, its severity, and the clinical response obtained. Divided dosage is usually employed. The following are suggested regimens:

**Adults**

*Short-term treatment:* 2 - 3mg daily for the first few days, subsequently reducing the daily dosage by 0.25 or 0.5mg every 2 - 5 days, depending upon the response.

*Rheumatoid arthritis:* 0.5mg - 2mg daily. For maintenance therapy, the lowest effective dosage is used.

*Most other conditions:* 1.5 - 5mg daily for 1 - 3 weeks, then reducing to the minimum effective dosage. Larger doses may be needed for mixed connective tissue diseases and ulcerative colitis.
**Children**
A fraction of the adult dosage (e.g. 75% at 12 years, 50% at 7 years, 25% at 1 year) may be used, depending on body weight

**If you miss a dose**
If your dosing schedule is:

**One dose every other day**
- Take the missed dose as soon as possible.
- If you do not remember the missed dose until later, wait and take it the following morning.
- Skip a day and start your regular dosing schedule again.

**One dose a day**
- Take the missed dose as soon as possible.
- If you do not remember the missed dose until the next day, skip the missed dose.
- Do not take two doses at the same time.

**Several doses a day**
- Take the missed dose as soon as possible.
- If you do not remember the missed dose until your next dose is due, take the two doses together.

**Contraindications**
It should not be used in any individual having hypersensitivity reaction to betamethasone or to any other component in the preparation.
It is contraindicated in patients suffering from systemic infection, unless specific anti-infective therapy is employed.
For those receiving immunosuppressive doses of corticosteroids, where serum antibody response is diminished, live virus vaccines are better to be avoided.

**Precautions**
In treating oral disorders, the presence of an oral herpetic lesion must be ruled out prior to initiation of glucocorticoid therapy.
Adrenal cortical atrophy may develop during prolonged therapy; therefore, in patients who have received more than 1mg of betamethasone for a period greater than 3 weeks, withdrawal should not be abrupt. Clinical assessment of disease activity may be needed during withdrawal. If the disease is unlikely to relapse on withdrawal, but there is uncertainty about adrenal suppression, the dose may be reduced rapidly until reaching a daily dose of 1mg, thereafter, dose reduction should be slower to allow the HPA – axis to recover.
As with other corticosteroids, betamethasone should be used with great caution in the presence of infections. Similarly, patients already receiving betamethasone are more susceptible to infections.
Children and adolescents may be at increased risk of some adverse effects, specially growth retardation which may be irreversible. The elderly too may be at greater risk of some adverse effects; therefore, close supervision is required particularly on long-term treatment.
Frequent monitoring is required if there is a history of tuberculosis or x-ray changes, or if the patient is suffering from hypertension, recent myocardial infarction, congestive heart failure, liver failure, renal impairment, diabetes mellitus, including family history, severe affective disorders particularly when
there is a history of steroid-induced psychosis, corneal perforation, epilepsy, peptic ulcer, hypothyroidism, or history of steroid myopathy. Frequent monitoring is required also in patients suffering from osteoporosis as well as in post-menopausal women who are at special risk of developing osteoporosis.

**Pregnancy:** As with all drugs, betamethasone should only be prescribed when the benefits to the mother and child outweigh the risks such as in asthma. Risk of intra-uterine growth retardation may develop on prolonged or repeated systemic treatment. For pregnant women who are on corticosteroid therapy, corticosteroid cover is required during labour. Patients with fluid retention require close monitoring.

Betamethasone, given systemically, may result in a transient suppression of the foetal heart rate parameters and biophysical activity, that are widely used for the assessment of the foetal well-being.

**Lactation:** Corticosteroids may pass into breast milk, although no data is available for betamethasone. Infants of mothers taking high doses of systemic corticosteroids for prolonged periods may have a degree of adrenal suppression.

**Side Effects**

The side effects may be minimized by using the lowest effective dose for the minimum period possible. The following have been reported infrequently:

- Gastrointestinal effects including dyspepsia, peptic ulceration probably with perforation, abdominal destension, acute pancreatitis, oesophageal ulceration, and candidiasis.

- Musculoskeletal effects including proximal myopathy, osteoporosis, vertebral and long bone fractures, avascular osteonecrosis, and tendon rapture.

- Endocrine effects including adrenal suppression, menstrual irregularities, amenorrhoea, hirsutism, weight gain, negative nitrogen and calcium balance, and increased appetite.

High doses may cause Cushing’s syndrome, with moon face, stria, and acne. This syndrome is usually reversible on withdrawal of treatment, but this must always be gradually tapered to avoid symptoms of acute adrenal insufficiency.

- Neuropsychiatric effects including euphoria, psychological dependence, depression, insomnia, increased intracranial pressure with papilloedema in children (usually after withdrawal), psychosis and aggregation of schizophrenia, and aggravation of epilepsy.

- Ophthalmic effects including glaucoma, papilloedema, posterior subcapsular cataracts, corneal or scleral thinning, and exacerbation of ophthalmic viral or fungal disease.

- Other side effects include increased susceptibility to and severity of infection, impaired healing, skin atrophy, bruising, striae, telangiectasia, acne, myocardial rupture following recent myocardial infarction, fluid and electrolyte disturbances, leucocytosis, hypersensitivity reactions (including anaphylaxis), thromboembolism, nausea, malaise, and hiccups.

**Overdosage**

Acute ingestion, even in massive doses, is rarely a clinical problem, as well as, acute overdosage probably requires no treatment, and requires no tapering as in withdrawal of patients on longterm therapy. If necessary, general symptomatic and supportive measures should be carried out.
Drug Interactions
Increased risk of hypokalaemia is expected upon concurrent administration of betamethasone with acetazolamide, carbenoxolone, cardiac glycosides, loop diuretics, thiazide and thiazide-related diuretics (antagonises as well the diuretic effect of diuretics), theophylline, amphotericin (avoid concomitant use unless amphotericin is needed to control reactions), and high doses beta2-sympathomimetics.
Upon concurrent administration with betamethasone, the hypoglycaemic effect of antidiabetics may be antagonised, as well as the hypotensive effects of some other drugs may be antagonized also, these include ACE inhibitors, adrenergic neurone blockers, alpha-blockers, angiotensin-II receptor antagonists, beta-blockers, calcium-channel blockers, clonidine, diazoxide, hydralazine, methylldopa, minoxidil, moxonidine, nitrates and nitroprusside.
Metabolism of betamethasone may be accelerated leading to reduction in its efficacy upon concurrent administration with aminogluthethimide, barbiturates, carbamazepine, phenytoin, primidone and rifamcins. However, metabolism of betamethasone may be possibly inhibited by erythromycin and ketoconazole.
Increased risk of gastrointestinal bleeding and ulceration is expected when betamethasone is given with NSAIDs or aspirin, as well as, betamethasone may reduce the plasma concentration of aspirin and other salicylates.
Plasma concentration of betamethasone may possibly be increased by ritonavir or oral contraceptives that contain oestrogens.
Betamethasone may inhibit growth-promoting effect of somatropin.
High doses of betamethasone may impair the immune response to vaccines; therefore, avoid the concomitant use with live vaccines.
Increased risk of haematological toxicity is expected upon concurrent use with methotrexate.
If mifepristone is administered during treatment with betamethasone, its effect may be reduced for 3–4 days after taking mifepristone.
Betamethasone may either enhance (by high doses) or reduce the anticoagulant effect of coumarins.

Presentation
Betasone tablets: Pack of 20 tablets.
* Store at a temperature not exceeding 25°C, in a dry place.