

YSP BETAMETHASONE TABLET 0.5mg

Ingredient(s):

Each tablet contains:

Betamethasone 0.5mg

Pharmacodynamics:

1. Betamethasone is a glucocorticoid. It has 16 β -methyl group that enhances the anti-inflammatory action of the molecule and reduces the sodium and water retaining properties of the Fluorine atom bound at Carbon 9.
2. Betamethasone has the ability to decrease or prevent tissue response to an inflammatory processes by inhibiting the accumulation of inflammation cells, including macrophage and leukocytes at sites of inflammation. It can also inhibit phagocytosis, lysosomal enzyme release, and synthesis and/or release of several chemical mediator of inflammation.
3. Betamethasone is primarily used for its potent anti-inflammatory effects in disorders of many organ systems. In addition, it also modifies the body's immune response to diverse stimuli.
4. Betamethasone's anti-inflammatory property is stronger than other glucocorticoids. Its mineralocorticoid side effect is appreciably lower than drugs belonging to that group.
5. Betamethasone is a long-acting glucocorticoid with a half-life of 3 - 5 hours.

Pharmacokinetics:

1. Betamethasone is rapidly and almost completely absorbed from the gastrointestinal tract.
2. Primarily metabolized in the hepatic; also in renal and tissue; mostly to inactive metabolites and excreted in the urine, mainly as inactive metabolites.

Indication(s):

Acute and chronic rheumatic fever, rheumatoid arthritis, bronchial asthma, myolitis, dermatitis.

Dosage and Administration:

Usual adults dose: Initiate with 1.5 to 5mg. Maintenance dose: 0.5 to 1.5mg/day in divided doses 2 to 4 times daily, after meals or at bedtime. The daily dosage may be reduced by 0.25mg every 2 - 3 days until the lowest dosage, which will maintain an adequate clinical response, is reached. To be dispensed on physician's prescription.

Route of administration:

For oral administration.

Contraindication(s):

Betamethasone is contraindicated in patients with systemic fungal infections and those who have shown hypersensitivity to any component of this product. Unless considered life-saving, systemic administration of corticosteroid is contraindicated in patients with peptic ulcer, osteoporosis, psychoses or severe psychoneuroses. Live vaccines should not be given to patients receiving high dose systemic corticosteroid therapy. Killed vaccines or toxoids may be given although the response may be attenuated.

Side Effect(s) / Adverse Reaction(s):

Side effects of Betamethasone include fluid and electrolyte disturbances, muscle weakness, osteoporosis, peptic ulcer with possible perforation and hemorrhage, impaired wound healing, facial erythema, convulsions, menstrual irregularities, suppression of growth in children, decreased carbohydrate tolerance, increased intraocular pressure and negative nitrogen balance due to protein catabolism. Prolonged treatment with corticosteroids in high dosage is occasionally associated with subcapsular cataract, and skin thinning.

Precaution(s) / Warning(s):

1. Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used.
2. Corticosteroids should be given concomitantly with chemotherapeutic agents or antibiotics in the treatment of acute or chronic infections.
3. Should be given with caution in patients with gastric intestinal ulcer, kidney disorder, hypertension, and diabetes.
4. Patients should be supplemented with high protein diet during therapy.
5. Because of possibility of fluid retention, care must be taken when steroids are administered to patients with congestive heart failure.

6. Steroids may worsen diabetes mellitus, osteoporosis, hypertension, glaucoma and epilepsy.
7. 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.
8. Should be used only with great caution in elderly persons.
9. Pheochromocytoma crisis, which may be fatal, has been reported after administration of systemic corticosteroids. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation.

Pregnancy and Lactation:

The use of Betamethasone in pregnancy, nursing mothers, or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards, to the mother and embryo or fetus.

Interactions with Other Medicaments:

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.

Symptoms and Treatment for Overdosage, and Antidote(s):

There is no specific antidote for its overdosage, therefore, management of the patients should consist of symptomatic and supportive therapy.


Shelf-Life:

3 years from the date of manufacture.

Storage Condition(s):

Keep in a tight container. Store at temperature below 30°C. Protect from light and moisture.

Product Description & Packing(s):

A white color round tablet '  '

Plastic bottle of 500's, 1000's and 2000's (for export only).

Plastic bottle of 100's

Blister packing of 10's x 10 and 10's x 100.



Manufacturer and Product Registration Holder:
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