Adrenocortical Steroid

BFI MYS-001
R.O.C. Reg. No.:031695

BUFENCON Injection

Description: A white to off-white suspension.

Ingredients: Each ml contains:

Betamethasone (as dipropionate)	5mg
Betamethasone (as phosphate disodium)	2mg
Preservatives:	
Benzyl Alcohol	5mg
Methyl Paraben	1.8mg
Propyl Paraben	0.2mg

Pharmacology:

Pharmacodynamic:

Betamethasone decreases or prevents tissue responses to inflammatory processes, thereby reducing the development of symptoms of inflammation without affecting the underlying cause. It inhibits accumulation of inflammatory cells including macrophages and leukocytes at sites of inflammation.

Pharmacokinetic:

Prompt therapeutic activity in corticosteroid-responsive conditions is achieved by the soluble ester, betamethasone sodium phosphate, which is quickly absorbed after injection. Sustained activity is provided by betamethasone dipropionate, which is only slightly soluble and affords a repository for slow absorption, thereby controlling symptoms over a prolonged period.

Betamethasone is primarily metabolized in the liver, others in the kidney and tissue, to mostly inactive metabolites which are excreted in the urine.

Indications:

Rheumatic disorders: As adjunctive therapy for short term administration (to tide the patients over an acute episode or exacerbation) in: post traumatic osteoarthritis; synovitis of osteoarthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); acute and subacute bursitis; epicondylitis; acute nonspecific tenosynovitis; acute gouty arthritis; psoriatic arthritis; ankylosing spondylitis.

Collagen disease: During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus; acute rheumatic carditis.

Allergic states: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in bronchial asthma; contact dermatitis; atopic dermatitis; serum sickness; seasonal perennial allergic rhinitis; drug hypersensitivity reactions; urticarial transfusion reactions; acute noninfectious laryngeal edema (epinephrine is the drug of first choice)

Route of administration:

I.M. and local administration (Intra-articular injection, Intradermal injection, Intralesional injection) only.

Dosage and administration:

It should be emphasized that Dosage Requirements are variable and must be individualised on the basis of the disease under treatment and the response of the patient.

Strict aseptic technique is mandatory in the use of this product.

Intramuscular Injection: 1.0 ml repeated according to the response of the condition.

1. Effective control of symptoms with 1.0-2.0 ml is obtained in bronchial asthma, hay fever, allergic bronchitis and allergic rhinitis. Onset of relief has occurred within a few hours of intramuscular injection.
2. In the treatment of acute or chronic bursitis, excellent results are obtained with intramuscular injection of 1.0-2.0 ml, repeated as necessary.

Local administration:

1. Intra-articular Injection:
   Large joints (knee, hip, shoulder): 1.0-2.0 ml
   Medium joints (below the wrist, ankle): 0.5-1.0 ml
   Small joints (foot, hand, chest): 0.25-0.5 ml
2. Intradermal Injection:
   For dermatologic conditions, 0.2 ml/cm^2 with a tuberculin syringe and a small 26-gauge needle is recommended. The total amount of Bufencon Injection injected at all sites each week should not exceed 1.0 ml.
3. Intralesional Injection:
   A tuberculin syringe with a small 25-gauge needle is suitable for most injections into the foot. Recommended doses at intervals of approximately one week: bursitis under heloma durum or molle, 0.25-0.5 ml; bursitis under calcaneal spur, 0.5 ml; bursitis over hallux rigidus, 0.5 ml; bursitis over digiti quinti varus, 0.5 ml; synovial cyst, 0.25-0.5 ml; Morton's neuralgia (metatarsalgia), 0.25-0.5 ml; tenosynovitis, 0.5 ml; periostitis of cuboid, 0.5 ml; acute gouty arthritis, 0.5-1.0 ml.

To be administered only by a physician.

Contraindications:

Contraindicated in patients hypersensitive to Betamethasone, other corticosteroids and to any components of this product.

As with other corticosteroid preparations, Bufencon Injection is contra-indicated in systemic infections. Corticosteroids should not be injected into unstable joints, infected areas, or intervertebral spaces.

Precautions:

1. Bufencon Injection is not for intravenous use.
2. Long-term intramuscular administration of corticosteroids is known to cause secondary adrenocortical insufficiency. Patients treated for extended periods should be given gradually reduced dosages.
3. When local or systemic infections are present, therapy with Bufencon Injection is not recommended.
4. This product contains two betamethasone esters one of which, betamethasone sodium phosphate disappears rapidly from the injection site. The potential systemic effect produced by the soluble portion should therefore be taken into account by the physician when using the drug.
5. While on corticosteroid therapy patients should not be vaccinated againts smallpox. Other immunization procedures should not be undertaken in patients who are on corticosteroids, especially in high doses because of possible hazards of neurological complications and lack of antibody response.
6. Because rare instances of anaphylactoid reactions have occured in patients receiving parenteral corticosteroids therapy, appropriate precautionary measures should be taken prior to administration, especially when the patients has allergy to any drug.
7. Intra-articular injection of corticosteroid may produce systemic as well as local effects. Appropriate examination of any joint fluid present is necessary to exclude a septic process.
8. The injection contains polysorbate 80. Premature life-threatening syndrome consisting of liver and renal failure, pulmonary deterioration, thrombocytopenia, and ascites has been associated with an injectable vitamin E products containing polysorbate 80.
9. Since adequate human reproduction have not been studied with corticosteroids, the use of this drug in pregnancy, nursing mothers, or women of child bearing potential requires that the risk benefit ratio should be considered.

Warnings
As this preparation contains benzyl alcohol, its use should be avoided in children under two years of age. Not to be used in neonates.

Interaction with Other Medicaments:

1. Concurrent use of phenobarbital, phenytoin, rifampin or ephedrine may enhance the metabolism of corticosteroids thus reducing their therapeutic effects.
2. Patients receiving both a corticosteroid and an estrogen should be observed for excessive corticosteroid effects.
3. Concurrent use of corticosteroids with potassium-depleting diuretics may enhance hypokalemia. Concurrent use of corticosteroids with cardiac glycosides may enhance the possibility of arrhythmias or digitalis toxicity associated with hypokalemia. Corticosteroids may enhance the potassium depletion caused by amphotericin B. In all patients taking any of these drug therapy combinations, serum electrolyte determinations, particularly potassium levels, should be monitored closely.
4. Concurrent use of corticosteroids with coumarin-type anticoagulants may increase or decrease the anticoagulant effects, possibly requiring adjustment in dosage.
5. Combined effects of non-steroidal anti-inflammatory drugs or alcohol with glucocorticosteroids may result in an increased occurrence or increased severity of gastrointestinal ulceration.
6. Corticosteroids may decrease blood salicylate concentrations. Acetylsalicylic acid should be used cautiously in conjunction with corticosteroids in hypothrombinemia.
7. Dosage adjustment of an antidiabetic drug may be necessary when corticosteroids are given to diabetics.
8. Concomitant glucocoticosteroid therapy may inhibit the response to somatotropin.

Adverse reactions:

Fluid and electrolyte disturbances: sodium retention; fluid retention; congestive heart failure in susceptible patients; potassium loss; hypokalemic alkalosis; hypertension.

Musculoskeletal: muscle weakness; steroid myopathy; loss of muscle mass; osteoporosis; vertibral compression fractures; aseptic necrosis of femoral and humeral heads; pathologic fractures of long bones.

Gastrointestinal: peptic ulcer with possible subsequent perforation and hemorrhage; pancreatitis; abdominal distention; ulcerative esophagitis.

Dermatologic: impaired wound healing; thin fragile skin; petechiae and ecchymoses; facial erythema; increased sweating; may suppress reaction to skin tests.

Neurological: convulsions; increased intracranial pressure with papellidema (pseudotumor cerebri) usually after treatment; vertigo; headache.

Endocrine: menstrual irrigularities; development of cushingoid state; suppression of growth in children; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, trauma, surgery, or illness; decreased carbohydrate tolerance; manifestation of latent diabetes mellitus; increased requirements for insulin or oral hypoglycemic agents in diabetics.

Ophthalmologics: posterior subcapsular cataracts; increased intraocular pressure; glaucoma; exophthalmos.

Metabolic: negative nitrogen balance due to protein catabolism.

The following adverse reactions are related to parenteral corticosteroid therapy. Rare instances of blindness associated with intralesional therapy around the face and head; hyperpigmentation or hypopigmentation; subcutaneous and cutaneous atrophy; sterile abscess; post-injection flare (following intra-articular use); Charcot-like arthropathy.

Pregnancy and Lactation:

Since adequate human reproduction studies have not been studied with corticosteroids, the use of this drug in pregnancy, nursing mothers, or women of child bearing potential requires that the risk benefit ratio should be considered.

Symptoms and treatment for overdosage, and antidote(s), if any:

A single overdose of a corticosteroid would not be expected to produce acute symptoms. Hypercorticoid effects are not anticipated unless there has been repeated administration of high doses.

Systemic effects of chronic overdosage with steroids include effects on sodium and water retention, increased appetite, mobilisation of calcium and phosphorus with osteoporosis, nitrogen depletion, hyperglycaemia, effects on tissue repair, increased susceptibility to infection, adrenal insufficiency, adrenal cortex hyperactivity, mental and neurological disturbances and muscular weakness.

In case of an acute overdose, maintain adequate fluid intake and monitor electrolytes in serum and urine, with particular attention to sodium and potassium balance. In case of chronic toxicity, slowly withdraw the drug. Treat electrolyte imbalance if necessary.

Incompatibilities:

Do not mix with diluents or local anesthetics containing preservatives (eg. paraben, phenol) because flocculation of suspension may result

Storage conditions:

Store at temperature not exceeding 30℃.
Shake well before use. Protect from light.
Avoid freezing.

Shelf-life:

3 years

Packaging:

1 mlx50 Ampules/Box; 5 mlx10 Vials/Box

Manufacturer:
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