Adrenocortical Steroid

BFI SGP-002
R.O.C. Reg. No.:031695

BUFENCON Injection

Bufencon Injection provides a unique combination of highly soluble and slightly soluble esters of betamethasone that produces marked, prompt, and sustained anti-inflammatory, anti-rheumatic, and anti-allergic effects.

INGREDIENTS:

Each mL contains:

Betamethasone (as dipropionate) ..... 5 mg
Betamethasone (as phosphate disodium) ..... 2 mg

ACTIONS:

1. 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.
2. 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.
3. Betamethasone is primarily metabolized in the liver, others in the kidney and tissue, to mostly inactive metabolites which are excreted in the urine.

INDICATIONS:

Musculoskeletal and soft tissue inflammatory conditions, allergic dermatologic conditions, and collagen diseases.

DOSAGE AND ADMINISTRATION:

Intramuscular Injection: 1.0mL 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:

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. Since adequate human reproduction have not been studied with corticosteroids, the use of this drug in pregnancy, nursing mothers, or women of childbearing potential requires that the risk-benefit ratio should be considered.
5. Visual disturbance: Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

DRUG INTERACTIONS:

1. Betamethasone may reduce the plasma levels of salicylates.
2. Phenobarbitone, by reducing liver enzymes, may increase the clearance of betamethasone.
3. Phenytoin may alter the metabolism of corticosteroids.
4. The hyperglycaemic effect of betamethasone may offset the hypoglycaemic effect of oral antidiabetic drugs.

ADVERSE EFFECTS:

Fluid and electrolyte, musculoskeletal, gastrointestinal, dermatologic, neurologic, endocrine, vision blurred, ophthalmic and metabolic disturbances may occur.

PACKAGINGS:

Box of 1 mL x 50 Ampules.
Box of 5 mL x 10 Vials.

Manufacturer:
YUNG SHIN PHARMACEUTICAL IND. CO., LTD.
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