

## PRESCRIBING INFORMATION – PLEASE RETAIN FOR FUTURE REFERENCE

**Aristospan**<sup>®</sup> Triamcinolone Hexacetonide

## Glucocorticoid

**Action:** Naturally occurring glucocorticoids, which also have salt-retaining properties, are used as replacement therapy in adrenal-cortical deficiency states. Their synthetic analogs are primarily employed for their potent anti-inflammatory effects in disorders of many body organs. Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

ARISTOSPAN is not rapidly removed from the site of injection after intra-articular administration, nor is it rapidly metabolized *in situ*.

**Pharmacology:** ARISTOSPAN is a potent glucocorticoid, possessing the anti-inflammatory corticotropin suppressing, protein-catabolic and carbohydrate-storing activities characteristic of that class of drug.

The pharmacological action of triamcinolone hexacetonide has been shown to be less intense and more prolonged, but qualitatively the same as triamcinolone acetonide. It has been determined that the activity of triamcinolone hexacetonide is ascribable to the slow release of triamcinolone acetonide through hydrolysis. Following this reaction, the pharmacology is identical to that of the parent compound, triamcinolone acetonide.

**Indications: Intra-articular.** ARISTOSPAN is indicated for treatment of synovitis of osteoarthritis, acute and subacute bursitis, epicondylitis, post-traumatic osteoarthritis, rheumatoid arthritis, acute gouty arthritis, acute nonspecific tenosynovitis.

Since ARISTOSPAN has low solubility, if a more immediate therapeutic effect is desired, then a more soluble corticosteroid should be administered locally or systemically.

**Contraindications:** Should not be used when Systemic fungal infection is present.

**Warnings:**

1. ARISTOSPAN should not be given intravenously.
2. Active, latent or questionably healed tuberculosis, ocular herpes simplex and acute psychosis are considered to be conditions which require caution when glucocorticoid therapy is utilized.
3. **Pregnancy:** In pregnancy, particularly during the first trimester, steroids should be considered only when the benefits outweigh the risks involved, since fetal abnormalities have been observed in experimental animals.
4. Steroids should be used with caution in cases of psychic disturbances, in acute glomerulonephritis, active or latent peptic ulcer, myasthenia gravis, osteoporosis, fresh intestinal anastomoses, diverticulitis, thrombophlebitis, diabetes mellitus, hyperthyroidism, acute coronary artery disease, hypertension, limited cardiac reserve or systemic infections including exanthematous diseases.

5. Caution regarding vaccination against smallpox and other immunization procedures is advised.
6. Ophthalmic complications during prolonged corticosteroid therapy have been observed. These include posterior subcapsular cataract, glaucoma and possible damage to optic nerves and enhancement of secondary ocular infections due to fungi or virus.
7. Calcium excretion is increased during corticosteroid therapy.
8. Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.
9. Appropriate examination of any joint fluid present is necessary to avoid a septic process.

**Precautions: General:** Precautions common to all corticosteroid therapy should be observed:

1. If severe reactions, anaphylactoid reactions or idiosyncrasies occur, therapy should be discontinued and appropriate measures instituted.
2. Since corticosteroids depress adrenocortical function, therapy should be withdrawn gradually after prolonged treatment.
3. When patients on ARISTOSPAN for up to one (sometimes two) years after discontinuation are subjected to unusual stress (trauma, surgery), administration of a soluble corticosteroid should be considered.
4. Corticosteroid therapy may obscure symptoms of developing infectious disease. If infection occurs, appropriate antimicrobial measures should be taken.
5. Growth suppression of children is possible during prolonged therapy.
6. Corticosteroid therapy provides symptomatic treatment and does not obviate the need for conventional measures.
7. Infants of mothers who have received adrenocortical hormones during pregnancy should be observed closely for signs of hypoadrenalism and corrective hormone therapy instituted if such signs are evident. Since spontaneous remission of some diseases, such as rheumatoid arthritis, may occur during pregnancy, effort should be made to avoid corticosteroid therapy during pregnancy.
8. Corticosteroids may suppress reactions to skin tests.
9. ASA should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia.
10. There is an enhanced effect of corticosteroids in patients with hypothyroidism and in those with cirrhosis.

**Intra-Articular Use:** The prolonged and repeated use of glucocorticoids in weight bearing joints may result in further joint degeneration. This may be related to increased use of still-diseased joints following relief of pain and other symptoms, or it may be due to inhibition by corticosteroid of protein synthesis in articular cartilage. It is inadvisable to inject unstable joints; repeated injections may, in some cases, result in instability of the joint.

Inadvertent injection into the soft tissues around the joint may lead to an increased incidence of systemic effect. As with all intra-articular injections, care should be taken to avoid entering a blood vessel.

A marked increase in pain, accompanied by local swelling, further restriction of joint motion, fever and malaise occurring after intra-articular injection is suggestive of septic arthritis. If this complication

appears and the diagnosis of sepsis is confirmed, antimicrobial therapy should be instituted immediately and continued for at least seven to ten days after clinical evidence of infection has disappeared.

Over-distention of the joint capsule and deposition of the steroid along the needle track should be avoided.

Patients should be advised not to overuse treated joints in which symptomatic benefit has been obtained as long as the inflammatory process remains active.

#### **Adverse Reactions:**

**Intra-Articular:** As with all glucocorticoids, an exacerbation of symptoms or "flare-up" may occur following injection. Local atrophy, burning, flushing and swelling may occur.

Charcot-like arthropathy may occur.

Temporary blindness associated with therapy around the face and head have been reported following the intralesional administration of corticosteroids, particularly around the eyes and nose.

**Systemic Effects** have occurred infrequently with ARISTOSPAN (triamcinolone hexacetonide), but, nevertheless, the physician should observe the patient for the following:

**Specific Triamcinolone Effects:** Certain systemic effects may occur that do not occur or may occur less frequently with other corticosteroids. These include:

1. A depression of appetite, in contrast to voracious appetite ordinarily encountered with other glucocorticoids.
2. Most common corticosteroids may cause euphoria whereas triamcinolone may cause a mood depression.
3. Common glucocorticoids cause sodium retention and edema, but triamcinolone may produce a mild early diuresis, making edema uncommon.
4. A myopathy with muscle weakness involving the muscles of the thighs, pelvis and lower back may occur more frequently with triamcinolone than with other corticosteroids.

**General Glucocorticoid Effects:** ARISTOSPAN may produce adverse effects common to all glucocorticoids: Cushingoid changes such as acne, flushing, moon face, hirsutism, etc.; endocrinologic effects such as amenorrhea, menstrual irregularity, aggravation of pre-existing diabetes mellitus and/or precipitation of latent diabetes mellitus; skeletal changes such as osteoporosis, spontaneous fractures, aseptic necrosis of the hip, humerus and metacarpals; psychic disturbances, insomnia, headache, increased intracranial pressure with papilledema (pseudotumor cerebri), convulsions; exophthalmos, increased intraocular tension, subcapsular cataracts, peptic ulcer with possible perforation and hemorrhage; ulcerative esophagitis; thromboembolic disease, ecchymoses, purpura, leukopenia, negative nitrogen balance; hypertension, and rarely, necrotizing angitis and acute pancreatitis. The occurrence of these systemic effects is unlikely when ARISTOSPAN is used as recommended.

**Symptoms and Treatment of Overdosage:** There is no satisfactory treatment or antidote known.

**Dosage and Administration:** Strict aseptic administration technique is mandatory. Topical ethyl chloride may be used locally before injection. The vial should be gently agitated to achieve uniform suspension before each use. Since ARISTOSPAN Suspension has been designed for ease of administration, a small bore needle (25 to 26 gauge) may be used.

**Intra-Articular:** Average dose is 2 to 20 mg. (0.1 mL to 1.0 mL)

The dose depends on the size of the joint to be injected, the degree of inflammation and the amount of fluid present. In general, large joints (such as knee, hip, shoulder) require 10 to 20 mg. For small joints (such as interphalangeal, metacarpophalangeal), 2 to 6 mg may be employed. When the amount of synovial fluid is increased, aspiration may be performed before administering ARISTOSPAN. Subsequent dosage and frequency of injections can best be judged by clinical response.

The usual frequency of injection into a single joint is every three or four weeks, and injection more frequently than that is generally not advisable. To avoid possible joint destruction from repeated use of intra-articular corticosteroids, injection should be as infrequent as possible, consistent with adequate patient care. Attention should be paid to avoid deposition of drug along the needle path, which might produce atrophy.

**Supplied:** Each mL of sterile suspension contains: triamcinolone hexacetonide 20 mg. Nonmedicinal ingredients: benzyl alcohol (as preservative) 0.90% w/v, polysorbate 80, sorbitol solution and water for injection. Tartrazine-free. Vials of 1 mL.

**FULL PRESCRIBING INFORMATION AVAILABLE ON REQUEST**



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