HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TRIVARIS™ safely and effectively. See full prescribing information for TRIVARIS™.

TRIVARIS™ (triamcinolone acetonide injectable suspension) 80 mg/mL
Initial U.S. Approval: 1957

--------INDICATIONS AND USAGE----------
TRIVARIS™ is a corticosteroid indicated for:
- Ophthalmic Use (1.1)
- Intramuscular Use (1.2)
- Intra-articular Use (1.3)

----DOSAGE AND ADMINISTRATION-----
- Intravitreal dosing: 4 mg per 0.05 mL (50 microliters of 80 mg/mL suspension). (2.3)
- Intramuscular dosing: Initial dose is 60 mg injected into the gluteal muscle. Eight injections are required to administer a 60 mg dose. (2.4).
- Intra-articular dosing: 2.5 to 5 mg for smaller joints and from 5 to 15 mg for larger joints depending on the disease being treated. (2.5)

---DOSAGE FORMS AND STRENGTHS----
- Single-use syringe containing 8 mg (80 mg/mL) of triamcinolone acetonide suspension. (3)

----------CONTRAINDICATIONS----------
- Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura. (4.1)
- Corticosteroids should not be used in cerebral malaria. (4.2)

-----WARNINGS AND PRECAUTIONS-----
- **TRIVARIS™** is a suspension; it should not be administered intravenously. (5.1)
- Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and hyperglycemia. Monitor patients for these conditions and taper doses gradually. (5.2)
- Infections: Increased susceptibility to new infection and increased risk of exacerbation, dissemination, or reactivation of latent infection. (5.3)
- Ophthalmic effects: May include cataracts, infections, and glaucoma. Monitor intraocular pressure. (5.4)
- Elevated blood pressure, salt and water retention, and hypokalemia: Monitor blood pressure and sodium, potassium serum levels. (5.5)
- Behavioral and mood disturbances: May include euphoria, insomnia, mood swings, personality changes, severe depression, and psychosis. (5.6)
- GI perforation: Increased risk in patients with certain GI disorders. (5.7)
- Decreases in bone density: Monitor bone density in patients receiving long term corticosteroid therapy. (5.8)
- Live or live attenuated vaccines: Do not administer to patients receiving immunosuppressive doses of corticosteroids. (5.9)
- Negative effects on growth and development: Monitor pediatric patients on long-term corticosteroid therapy. (5.10)
- Use in pregnancy: Fetal harm can occur with first trimester use. (5.11)
- Weight gain: May cause increased appetite. (5.12)

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1-800-433-8871 or www.allergan.com or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------**DRUG INTERACTIONS**----------
- NSAIDS including aspirin and salicylates: Increased risk of gastrointestinal side effects. (7.14)

SEE 17 FOR PATIENT COUNSELING INFORMATION.
REVISED: MAY 2008

*FULL PRESCRIBING INFORMATION: CONTENTS**

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Ophthalmic Use

TRIVARIS™ (triamcinolone acetonide injectable suspension) 80 mg/mL is indicated for:

- sympathetic ophthalmia,
- temporal arteritis,
- uveitis, and
- ocular inflammatory conditions unresponsive to topical corticosteroids.

1.2 Intramuscular Use

Where oral therapy is not feasible, **TRIVARIS™** (triamcinolone acetonide injectable suspension) 80 mg/mL is indicated for intramuscular use as follows:

Allergic states: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopic dermatitis, contact dermatitis, drug hypersensitivity reactions, perennial or seasonal allergic rhinitis, serum sickness, transfusion reactions.

Dermatologic diseases: Bullous dermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome).

Endocrine disorders: Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance), congenital adrenal hyperplasia, hypercalcemia associated with cancer, nonsuppurative thyroiditis.

Gastrointestinal diseases: To tide the patient over a critical period of the disease in regional enteritis and ulcerative colitis.

Hematologic disorders: Acquired (autoimmune) hemolytic anemia, Diamond-Blackfan anemia, pure red cell aplasia, selected cases of secondary thrombocytopenia.

Miscellaneous: Trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used with appropriate antituberculous chemotherapy.

Neoplastic diseases: For the palliative management of leukemias and lymphomas.

Nervous system: Acute exacerbations of multiple sclerosis; cerebral edema associated with primary or metastatic brain tumor, craniotomy, or head injury.

Renal diseases: To induce diuresis or remission of proteinuria in idiopathic nephrotic syndrome or that due to lupus erythematosus.

Respiratory diseases: Berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, idiopathic eosinophilic pneumonias, symptomatic sarcoidosis.

Rheumatic disorders: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis; acute rheumatic carditis; ankylosing spondylitis; psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). For the treatment of dermatomyositis, polymyositis, and systemic lupus erythematosus.

1.3 Intra-articular Use

The intra-articular or soft tissue administration of **TRIVARIS™** (triamcinolone acetonide injectable

suspension) 80 mg/mL is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, synovitis of osteoarthritis.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The initial dose of **TRIVARIS™** (triamcinolone acetonide injectable suspension) 80 mg/mL may vary from 2.5 mg to 100 mg per day depending on the specific disease entity being treated (see **DOSAGE AND ADMINISTRATION,** 2.3**,** 2.4, 2.5). However, in certain overwhelming, acute, life threatening situations, administration in dosages exceeding the usual dosages may be justified and may be in multiples of the oral dosages. It should be emphasized that dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient.

After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. Situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient's individual drug responsiveness, and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment. In this latter situation it may be necessary to increase the dosage of the corticosteroid for a period of time consistent with the patient's condition. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually, rather than abruptly.

2.2 General Administration

Strict Aseptic Technique Is Mandatory. Careful technique should be employed to avoid the possibility of entering a blood vessel or introducing infection.

TRIVARIS™ should be inspected visually for particulate matter and discoloration prior to administration.

Always allow the pre-filled glass syringe to sit at room temperature for at least 30 minutes before the procedure.

2.3 Intravitreal Dosing

The recommended intravitreal dose is a single injection of 4 mg per 0.05 mL (i.e., 50 microliters of 80 mg/mL suspension).

Preparation for Intravitreal Injection

TRIVARIS™ is available without an attached needle. Therefore, it is necessary to firmly attach a desired needle to the syringe. A 27 gauge ½ inch needle is suggested. Prepare the proper volume of **TRIVARIS™** to be injected by advancing the plunger to the single line marked on the pre-filled glass syringe shaft. Hold the syringe and the needle at an angle and express excess gel suspension over a sterile surface. The plunger is correctly positioned when white compound is no longer visible between the plunger and the fill line on the syringe. This will provide the recommended dose of 4 mg per 0.05 mL. Always check the needle to ensure it is firmly attached to the syringe before injecting the patient.

The intravitreal injection procedure should be carried out under controlled aseptic conditions which include the use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent). Adequate anesthesia and a broad-spectrum

microbicide should be given prior to the injection.

Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis. Monitoring may consist of a check for reperfusion of the optic nerve head immediately after the injection, tonometry within 30 minutes following the injection, and biomicroscopy between two and seven days following the injection. Patients should be instructed to report any symptoms suggestive of endophthalmitis without delay.

Each syringe should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new syringe should be used and the sterile field, syringe, gloves, drapes, and eyelid speculum and injection needles should be changed before **TRIVARIS™** is administered to the other eye.

2.4 Systemic Dosing

The suggested initial dose is 60 mg, **injected deeply into the gluteal muscle**. Atrophy of subcutaneous fat may occur if the injection is not properly given. Dosage is usually adjusted within the range of 40 to 80 mg, depending upon patient response and duration of relief. However, some patients may be well controlled on doses as low as 20 mg or less.

For adults, a minimum needle length of 1½ inches is recommended. In obese patients, a longer needle may be required. Use alternative sites for subsequent injections. Each syringe should only be used for a single treatment. Multiple injections are required to reach the recommended dose. In pediatric patients, the initial dose of triamcinolone may vary depending on the specific
disease entity being treated. The range of initial doses is 0.11 to 1.6 mg/kg/day in three or four divided doses (3.2 to 48 mg/m^{2}bsa/day).

For the purpose of comparison, the following is the equivalent milligram dosage of the various glucocorticoids:

Cortisone, 25	Triamcinolone, 4
Hydrocortisone, 20	Paramethasone, 2
Prednisolone, 5	Betamethasone, 0.75
Prednisone, 5	Dexamethasone, 0.75
Methylprednisolone, 4	

These dose relationships generally apply to oral or intravenous administration of these compounds. When these substances or their derivatives are injected intramuscularly or into joint spaces, their relative properties may be greatly altered.

Hay fever or pollen asthma: Patients with hay fever or pollen asthma who are not responding to pollen administration and other conventional therapy may obtain a remission of symptoms lasting throughout the pollen season after a single injection of 40 to 100 mg.

In the treatment of acute exacerbations of multiple sclerosis, daily doses of 160 mg of triamcinolone for a week followed by 64 mg every other day for one month, are recommended (see **WARNINGS AND PRECAUTIONS,** 5.12).

2.5 Intra-articular Dosing

A single local injection of triamcinolone acetonide is frequently sufficient, but several injections may be needed for adequate relief of symptoms.

Initial dose: 2.5 to 5 mg for smaller joints and from 5 to 15 mg for larger joints, depending on the specific disease entity being treated. For adults, doses up to 10 mg for smaller areas and up to 40 mg for larger areas have usually been sufficient. Single

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