OMNIPRED® (prednisolone acetate ophthalmic suspension) is an adrenocortical steroid product prepared as sterile ophthalmic suspension. The active ingredient is represented by the chemical structure:

Established name: Prednisolone Acetate

Chemical name: Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-,(11/2H9252)-.

Each mL contains: Active: prednisolone acetate 1.0%. Preservative: benzalkonium chloride 0.01%. Vehicle: hypromellose. Inactives: dibasic sodium phosphate, polysorbate 80, edetate disodium, glycerin, citric acid and/or sodium hydroxide (to adjust pH), purified water.

CLINICAL PHARMACOLOGY: Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. There is no generally accepted explanation for the mechanism of action of ocular corticosteroids. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Corticosteroids are capable of producing a rise in intraocular pressure.

INDICATIONS AND USAGE: Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the eye; for the reduction of postoperative inflammation; to reduce edema and inflammation; corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies.

CONTRAINDICATIONS: OMNIPRED® (prednisolone acetate ophthalmic suspension) is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and variola, and in individual hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

WARNINGS: FOR TOPICAL OPHTHALMIC USE ONLY. Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, posterior subcapsular cataract formation, and delayed wound healing. Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticism after use of topical steroids. Corticosteroid-containing preparations have also been reported to cause acute anterior uveitis and perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids.

The development of secondary ocular infection (bacterial, fungal and viral) has occurred. Fungal and viral infections of the corneas are particularly prone to develop coincidently with long-term applications of steroid. The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used (SEE WARNINGS). DOSEAGE AND ADMINISTRATION: SHAKE WELL BEFORE USING. Two drops topically in the eye(s) four times daily. In cases of bacterial infections, concomitant use of anti-infective agents is mandatory. Care should be taken not to discontinue therapy prematurely. If signs and symptoms fail to improve after two days, the patient should be re-evaluated. The dosing of OMNIPRED® suspension may be reduced, but care should be taken not to discontinue therapy prematurely. In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of applications.

HOW SUPPLIED: OMNIPRED® (prednisolone acetate ophthalmic suspension) is supplied in a white, round low density polyethylene DROP-TAINER® dispenser with a natural low density polyethylene dispensing plug and pink polypropylene cap. Removable tamper-evident band around the closure and neck area of the package.

STORAGE: STORE at 8° - 24°C (46° - 75°F) in an UPRIGHT position.

Information for Patients: If inflammation or pain persists longer than 48 hours or becomes aggravated, the patient should be advised to discontinue use of the medication and consult a physician. This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the bottle tip to eyelids or to any other surface. The use of this bottle by more than one person may spread infection. Keep bottle tightly closed when not in use. Keep out of the reach of children.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No studies have been conducted in animals or in humans to evaluate the potential of these effects. Pregnancy: Teratogenic effects. Pregnancy Category C. Prednisolone has been shown to be teratogenic in mice when given in doses 1-10 times the human dose. Dexamethasone, hydrocortisone and prednisolone were ocularly applied to both eyes of pregnant mice five times per day on days 10 through 13 of gestation. A significant increase in the incidence of cleft palate was observed in the fetuses of the treated mice. There are no adequate and well controlled studies in pregnant women. OMNIPRED® (prednisolone acetate ophthalmic suspension) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from prednisolone acetate, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatic Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS: Adverse reactions include, in decreasing order of frequency, elevation of intraocular pressure (IOP) with possible development of glaucoma and infratrocar cataract formation, and delayed wound healing.

Intraocular pressure should be monitored regularly in patients receiving OMNIPRED® suspension.

If inflammation or pain persists longer than 48 hours or becomes aggravated, the patient should be advised to discontinue use of the medication and consult a physician. This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the bottle tip to eyelids or to any other surface. The use of this bottle by more than one person may spread infection. Keep bottle tightly closed when not in use. Keep out of the reach of children.