2232

PRED FORTE®

prednisolone acetate 1%
sterile ophthalmic suspension

DESCRIPTION

Each mL contains: prednisolone acetate 10 mg with: benzalkonium chloride 0.06 mg, polysorbate 80, boric acid, sodium citrate, sodium chloride, edetate disodium, hydroxypropyl methylcellulose and purified water.

ACTIONS

Prednisolone acetate is a glucocorticoid that, on the basis of weight, has 3 to 5 times the anti-inflammatory potency of hydrocortisone. Glucocorticoids inhibit the edema, fibrin deposition, capillary dilatation and phagocytic migration of the acute inflammatory response as well as capillary proliferation, deposition of collagen and scar formation.

INDICATIONS

For steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

CONTRAINDICATIONS

Acute untreated purulent ocular infections, acute superficial herpes simplex (dendritic keratitis), vaccinia, varicella and most other viral diseases of the cornea and conjunctiva, ocular tuberculosis, and fungal diseases of the eye, and sensitivity to any components of the formulation.

WARNINGS

1. In those diseases causing thinning of the cornea, perforation has been reported with the use of topical steroids. Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal or scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.
2. Since PRED FORTE® contains no antimicrobial, if infection is present appropriate measures must be taken to counteract the organisms involved.
3. Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids. Prolonged use may suppress the host immune response in ocular tissues and thus increase the possibility of secondary ocular infections.
4. Use of steroid medication in the treatment of patients with a history of herpes simplex requires caution and should be followed by frequent mandatory slit-lamp microscopy.
5. As fungal infections of the cornea have been reported coincidentally with long-term local steroid applications, fungal invasion may be suspected in any persistent corneal ulceration where a steroid has been used, or is in use.
6. Use of topical corticosteroids may cause increased intraocular pressure in certain individuals. This may result in glaucoma with damage to the optic nerve with defects in the visual fields. It is advisable that the intraocular pressure be checked frequently, particularly in patients with a history or presence of glaucoma.
7. **Use in Pregnancy** - Safety of intensive or protracted use of topical steroids during pregnancy has not been substantiated.
8. **Nursing Mothers -** It is not known whether topical administration could result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when PRED FORTE® is administered to a nursing woman taking into consideration the importance of the drug to the mother.
9. **Use in Children** - Safety and effectiveness of corticosteroids in children below the age of two years has not been established.

PRECAUTIONS

Posterior subcapsular cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids. Acute anterior uveitis may occur in susceptible individuals. The use of steroids after cataract surgery may delay healing and increase the incidence of filtering blebs. If signs of hypersensitivity or other serious reactions occur, discontinue use of this preparation. Cross-sensitivity among corticosteroids has been demonstrated (see **ADVERSE REACTIONS**).

ADVERSE REACTIONS

Increased intraocular pressure, with optic nerve damage, defects in the visual fields. Also posterior subcapsular cataract formation, secondary ocular infections from fungi or viruses liberated from ocular tissues, perforation of the globe when used in conditions where there is thinning of the cornea or sclera, and delayed wound healing. Corticosteroid-containing preparations can also cause acute anterior uveitis or perforation of the globe. Mydriasis, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids. Systemic side effects may occur with extensive use of steroids. There have been rare occurrences of systemic hypercorticoidism after use of topical steroids.

DOSAGE AND ADMINISTRATION

1 to 2 drops instilled into the conjunctival sac two to four times daily. During the initial 24 to 48 hours the dosage may be safely increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

HOW SUPPLIED

As a sterile suspension in 5 mL and 10 mL plastic dropper bottles.

Note: Store between 15° - 25°C; protect from freezing. Store upright. On prescription only. Keep out of the reach of children. **Shake well before use.**

ALLERGAN
Manufactured by:
Allergan Pharmaceuticals Ireland,
Westport, Ireland

INSERT STANDARDIZED,
4" X 10"
0284301

Part number: 72021UT10X
Drawing number: 0284301
V-code: 2232
Artwork is actual size
Drop template before processing

倍力特®眼用懸浮液1%
1% PRED FORTE® Ophthalmic Suspension
衛署藥輸字第018654號

每公撮含：
Prednisolone acetate 10 mg, benzalkonium chloride 0.06 mg, 以及 polysorbate 80, boric acid, sodium citrate, sodium chloride, edetate disodium , hydroxypropyl methylcellulose and purified water.

作用機轉：
Prednisolone acetate為glucocorticoid，依重量基準計，其消炎作用為hydrocortisone之3~5倍。glucocorticoids可抑制水腫，纖維蛋白沉積，微血管擴張，急性發炎反應時吞噬細胞的移動及微血管之增生，膠原沉積和瘢痕之形成。

適應症：
過敏性瞼緣炎，結合膜炎，潰瘍性角膜炎及異物入侵所引起之炎症。

禁忌症：急性未治療之化膿性眼發炎，急性淺部單純性疱疹(樹枝狀角膜炎)，牛痘，水痘，眼結核，及由黴菌、病毒感染之眼疾，或任何對主成分過敏者。

警語：

1. 有些疾病會引起角膜變薄，使用局部類固醇製劑時易造成角膜穿孔。
2. 因為本產品不含抑菌劑，因此當發生感染時必須適當的處置以對抗感染原。
3. 局部類固醇製劑可能會隱藏或加重急性化膿性感染之眼疾。
4. 以類固醇治療基質之單純性疱疹時必須非常小心，同時應常用裂隙燈顯微鏡檢查。
5. 曾有報告在長期使用局部類固醇時，同時發現有黴菌感染角膜，因此對於持續性角膜潰瘍，不論是曾經或正在使用局部類固醇治療，均須檢查是否有黴菌感染。
6. 有些人正在使用局部類固醇時會使眼內壓增加而導致視神經損壞，視野障礙，因此應時常檢查眼內壓。
7. 孕婦長期使用或增加劑量時的安全性仍未確定。
8. 用於授乳婦女：局部使用是否會導致足量的全身性吸收，於乳汁中產生可偵測出的量，至今仍未可知。當投與本品於授乳婦女時，應基於本品對該婦女的重要性考慮。
9. 用於小孩：投與類固醇於兩歲以下小兒的安全性和有效性仍未確立。

注意事項：
曾有報告當長期或增量使用局部眼用皮質類固醇後，會發生後囊下白內障。急性前房葡萄膜炎曾發生在易感體質。白內障手術後使用類固醇治療，可能會延後傷口癒合和增加滲入性水泡的發生。如有過敏的徵候或其他嚴重反應發生時，請停用該類固醇藥物。類固醇類藥物之間的交叉過敏反應已有前例可證(請參閱副作用段)。

副作用：
眼內壓增加，視神經損壞，視野障礙，後囊下白內障，或使徵菌、病毒引起眼睛再度感染。若角膜或鞏膜變薄而又使用類固醇時，易造成穿孔。使用含類固醇製劑也可能引起急性前房葡萄膜炎或眼球穿孔。偶爾也有散瞳、喪失視覺調節作用、和眼瞼下垂的報告。廣用類固醇時可能會產生全身性副作用。罕見有局部使用類固醇後產生全身性皮質類固醇亢進的病例。

用法用量：本藥須由醫師處方使用。每次1 ~ 2滴，每天2 ~ 4次，開始治療24 ~ 48小時內劑量可安全地增加到每小時兩滴，但須注意不可過早停藥。

包裝：5 mL, 10 mL塑膠滴瓶。

貯存方式：室溫下貯存，不需冷藏，置於小孩不可及之處，使用前請充分搖晃。

製造廠名: Allergan Pharmaceuticals Ireland
Castlebar Road, Westport, County Mayo, Ireland.
藥商：香港商愛力根有限公司台灣分公司
地址：台北市羅斯福路二段102號9樓
電話：(02)2366-9888

72021UT10X

Part number: 72021UT10X
Drawing number: 0284301
V-code: 2232
Artwork is actual size
Drop template before processing
Page 2 of 2

INSERT STANDARDIZED,
4" X 10"
0284301