



2237

PRED MILD®

prednisolone acetate 0.12%
sterile ophthalmic suspension

DESCRIPTION

Each mL contains: prednisolone acetate 1.2 mg with: benzalkonium chloride 0.04 mg, polysorbate 80, boric acid, sodium citrate, sodium metabisulfite, 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

Mild to moderate non-infectious allergic and inflammatory disorders of the lid, conjunctiva, cornea and sclera (including chemical and thermal burns).

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 MILD® 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 MILD® 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.

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. Systemic side effects may occur with extensive use of 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.**

© marks owned by Allergan, Inc.



Manufactured by:
Allergan Pharmaceuticals Ireland,
Westport, Ireland

Part number: 72026UT10X

Drawing number: 0284301

V-code: 2237

Artwork is actual size

Drop template before processing

Page 1 of 2

INSERT STANDARDIZED,
4" X 10"
0284301

倍得美眼用懸浮液0.12%

0.12% Pred Mild Ophthalmic Suspension
(Prednisolone acetate)

衛署藥輸字第018666號

本品每公撮含prednisolone acetate 1.2mg以及benzalkonium chloride 0.04mg, polysorbate 80, boric acid, sodium citrate, sodium metabisulfite, sodium chloride, edetate disodium, hydroxypropyl methylcellulose, purified water.

作用：Prednisolone acetate為glucocorticoid，依重量基準計，其消炎作用為hydrocortisone之3至5倍。Glucocorticoid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、膠元沉積和癰疽之形成。

適應症：過敏性睪緣炎、結合膜炎、潰瘍性角結膜炎及異物侵入所引起之炎症。

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，或任何對主成份過敏者。

警語：

1. 有些疾病會引起角膜變薄，已有報告指出使用局部類固醇製劑易造成角膜穿孔。已知使用局部類固醇製劑在不同的眼部疾病和長期使用，易導致角膜變薄，而使用局部類固醇在已知有角膜或鞏膜薄弱現象時，可能會引起穿孔的危險。
2. 因本品不含抗菌劑，故如有感染現象發生時，應採取適當的處理以對抗病原菌。
3. 局部類固醇製劑可能會隱蔽或加重急性化膿眼部感染。長期使用可能抑制眼部組織之免疫反應，因而可能增加繼發性眼部感染的可能性。
4. 以類固醇治療有單純性疱疹病史之病患時應小心注意，必須經常使用裂隙燈(slit-lamp)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的現象，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，都應注意是否有黴菌感染現象。
6. 某些特定病患使用局部類固醇，會使眼內壓增加而導致視神經損壞、視野障礙，尤其是有青光眼病史或曾出現青光眼現象的病人，應經常檢查其眼內壓。
7. 妊娠使用：妊娠期間之長期使用或增量使用局部類固醇的安全性仍未確立。
8. 授乳婦女使用：對於局部類固醇之使用是否足以產生全身性吸收，並於乳汁中產生可檢測之量，仍然未知，當本品使用在授乳婦女時，應審慎考慮本品對其之重要性。
9. 小兒使用：使用類固醇於兩歲以下孩童之安全性和有效性，仍未確立。

注意事項：

已有報告指出，在大量或長期使用眼用類固醇製劑，可能會導致後囊下白內障的產生。

副作用：

眼內壓增加、視神經損壞、視野障礙、後囊下白內障、或使黴菌、病毒引起眼睛再度感染。若鞏膜變薄而又使用類固醇時易造成穿孔。廣用類固醇時可能會產生全身性副作用。

用法用量：

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

包裝：

5mL，10mL塑膠滴瓶
本品應貯於室溫下(15°C - 20°C)：避光貯存。置於孩童不能及之處，使用前應搖勻。

製造廠：Allergan Pharmaceuticals (Ireland) Ltd.
廠址：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



72026UT10X

Part number: 72026UT10X

Drawing number: 0284301

V-code: 2237

Artwork is actual size

Drop template before processing

Page 2 of 2

INSERT STANDARDIZED,
4" X 10"
0284301