

得舒捷眼用凝膠劑

Dexagel

衛署藥輸字第 023681 號

成分：每公克含

Dexamethasone sodium phosphate	0.985 mg
Benzododecinium chloride	0.100 mg
Carbomer	3.000 mg
Sorbitol	49.000 mg
Disodium edetate	0.100 mg
Sodium hydroxide	1.46 - 1.54 mg
Water for injections in bulk	q.s.

特性

Dexagel 是 dexamethasone sodium phosphate 的一新處方製劑，由 Dr. Mann Pharma 所研製成的高黏度晶性透明膠液。成分 Carbomer 可增加處方的黏度，因此減慢眼睛中藥物的洗去，dexamethasone 在角膜組織、眼房水和淚腺的生體可用率增加，故治療發炎的作用較佳。

藥理作用

Dexamethasone 是一長效性皮質類固醇，生理半衰期是 36~54 小時。其經由與細胞內的類固醇接受體結合而顯現其作用，與接受體形成的複合物會影響細胞核 DNA 轉錄和蛋白質的合成。治療作用是基於其強效的抗發炎和免疫抑制特性。

適應症

急性結膜炎、過敏性結膜炎。

用法用量

本藥須由醫師處方使用。

開始時每 4 小時一次，滴入下結膜囊內，以後每天 3~4 次即可，治療時間不要超過 4 星期。

禁忌症

淺角膜炎、角膜炎、角膜潰瘍、眼瞼結核、眼瞼菌病、狹角性和廣角性青光眼，對本品任何成分過敏者。

注意事項

就像所有其他腎上腺類皮質素一樣，dexamethasone 由於其蛋白質異化作用，會影響病人對細菌的抵抗力。假如發生感染，只要感染經由特別的治療而安全地被治療，則不應使用 dexamethasone。除非發炎反應嚴重到絕對需要用抗發炎藥物治療。縱使依指示使用，亦可能有暫時的視力模糊，故駕駛和操作機器者宜注意。

副作用

極少數病人長期治療可能發生白內障和青光眼之虞。

糖尿病人的血糖濃度可能會升高。

請注意：以上的副作用可能發生於所有類固醇藥物，故病人應每星期接受眼科醫師檢查。

交互作用

未發現與其他藥物有交互作用，但如果與其他眼藥水或眼藥膏併用，請間隔 5 分鐘，本品應最後使用。

過量

點眼次數過於頻繁會有副作用增加之危險，例如眼內壓可能升高和晶狀體渾濁之虞。

貯存

不要存放於溫度 25°C 以上。

產品逾期不要使用，開啟後 4 星期應將剩餘的藥品丟棄。

包裝

100 公克以下軟管裝。

製造廠：Dr. Gerhard Mann Chem.-pharm. Fabrik GmbH

廠址：Brunsbütteler Damm 165-173, 13581 Berlin Germany

藥商：武昌貿易有限公司

地址：台北市南京西路 13 號 8 樓

Dr. Mann Pharma

Important! Read Carefully!

DEXAGEL

Composition

Active ingredients: 1 g contains dexamethasone sodium phosphate 0.985 mg, preserved with benzododecinium chloride 0.1 mg.

Other ingredients: Carbomer, Sorbitol, Disodium edetate, sodium hydroxide, water for injections.

Properties

Dexagel is a new formulation of dexamethasone sodium phosphate in the form of a viscous crystal-clear hydrogel developed by Dr. Mann Pharma GmbH, Berlin.

The ingredient carbomer increase the viscosity of formulation and thereby slows down the washout of the drug from eye. Bioavailability of dexamethasone in corneal tissue, aqueous humour and tear film is increased after application of the Dexagel, resulting in better action for treatment of inflammation.

Pharmacological Action

Dexamethasone is a longer effective corticosteroid. The biological half-life is 36-54 hours. Dexamethasone displays its effect via an intracellular binding to the steroid receptor. This dexamethasone-receptor complex influences the DNA transcription and protein synthesis in the cell nucleus. The therapeutic effects are based on its strong anti-inflammatory and immunosuppressive activity.

Indications

Non-bacterial inflammation of the cornea and conjunctiva.

As supplementary treatment to an antibiotic basic therapy in the presence of bacterial conjunctivitis and superinfected allergic conjunctivitis.

Dosage and administration

Instil into the conjunctival sac.

Initially, instil 1 drop every 4 hours into the lower conjunctival sac.

Afterwards, 3 to 4 daily applications are sufficient.

The duration of treatment should not exceed 4 weeks.

Contraindications

Herpes cornea superficialis; injuries and ulcerous processes of cornea; ocular tuberculosis; ophthalmic mycosis; ulcerous lesions of the cornea; narrow-and open-angle glaucoma; hypersensitivity to any ingredient of the medicinal product.

Precautions

Like all other corticoids, dexamethasone may impair the patient's antibacterial resistance owing to its protein-catabolic effect and, thus, may occasionally also promote and infection. If an infection occurs, treatment with dexamethasone should be discontinued as long as the infection has safely healed up under specific (and antibiotic) treatment, unless the inflammatory reaction is so severe that antiphlogistic treatment is absolutely necessary.

Even when used as indicated, this medicinal product may cause transient blurring of vision, and patients should exercise caution when driving vehicles or operating machinery.

Side effects

Under long-term treatment, glaucoma and cataract may develop in rare cases.

Diabetics may experience a rise in blood glucose level.

Please note: owing to the side effects mentioned above which may possibly occur with all corticosteroids, patients should be examined adequately by their ophthalmologist at least once weekly.

Drug interactions

Special interactions with other medicinal products have not been reported. Nevertheless if Dexagel is used along with other eye drops/ointments, there should be an application interval of approx. 5 minutes between the medications and Dexagel should always be the last medication to be administered.

Overdose

Overdosing due to frequent instillation increases the risk of side effects such as elevated intra-ocular pressure and the development of opacities of the lens.

Storage

Do not store at temperature exceeding 25°C.

Do not use this product beyond the expiry date. Discard any remaining content 4 weeks after opening the tube.

Presentation

Tube of 5 g.

Keep all medicines in a safe place out of the reach of children!

Dr. Gerhard Mann · Chem-pharm. Fabrik GmbH · D-13581 Berlin Germany