POST-OPERATIVE CATARACT KIT AND METHOD

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Abstract
A kit for use post-operatively by patients who have undergone cataract surgery and are unable to gather the medications and eyewear required for recovery, comprising a container for antibiotic and anti-inflammatory medications, special eyeglasses, an eye shield, and instructions for use of the contained products.
POST-OPERATIVE CATARACT KIT AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority of U.S. Provisional Patent Application 61/509,942 filed Jul. 20, 2011, the contents of which are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to systems and methods for providing post-operative treatment and, more particularly, to such systems and methods for providing continued treatment after cataract surgery.

BACKGROUND OF THE INVENTION

[0003] After cataract and other eye surgeries, antibiotics need to be administered every few hours for several days. In addition, other medications such as anti-inflammatory drugs also need to be administered frequently. The drugs are typically delivered to the ocular surface and the front of the eye in the form of eye drops. Currently, almost all cataract surgery is performed as outpatient or ambulatory surgery leaving the follow-up administration of anti-infective and anti-inflammatory medications to the patient or other in-home care giver.

[0004] While the patient invariably receives at least one prescription to fill for their drugs, they oftentimes require additional post-operative aids or devices to improve their recovery. For example, doctors will frequently provide sunglasses to combat light sensitivity and an eye shield to wear while sleeping. The various elements of post-operative cataract care are therefore known, but they have never been offered together in a comprehensive convenience kit.

[0005] Particularly, doctors usually do not fill prescription medication orders in-house. The prescriptions are filled through a pharmacy. The doctor is often relied upon to provide the protective hardware e.g., sunglasses and shields), but a doctor’s office or surgical center has a primary purpose of treating the patient and not necessarily supplying their patients with post-operative aids. A pharmacy, while likely to have a selection of sunglasses and other post-operative aids, is primarily a drug dispensary and the needed post-surgery aids may not be provided.

[0006] Lastly, a typical post cataract surgery course of treatment includes three prescription medications. Sometimes one or more of these three individually prescribed medications is not available at the pharmacy, requiring the patient to fill that prescription at another pharmacy or to call the doctor to alter their prescription to an equivalent/available medicine.

[0007] Post-operatively, patients of cataract surgery have impaired vision for a day or so and are encouraged not to drive for at least that time. Unless they have a caregiver that can collect the prescribed pharmaceuticals and the needed post-surgery aids, they may not receive the benefits of these products on a timely basis.

[0008] There is therefore a need for a convenient and reliable system and method to provide both the prescribed medications and all of the needed post-operative aids to a patient.

SUMMARY OF THE INVENTION

[0009] In accordance with one form, of this invention there is provided an improved convenience kit having both prescribed eye medications and protective devices to improve a patient’s overall treatment after cataract surgery. The present invention offers convenient combination therapy for improving overall post ocular surgery treatment and also providing protective hardware to reduce the likelihood of irritation or discomfort while the patient heals. The kit of the invention comprises a topical antibiotic, a topical non-steroidal anti-inflammatory medication, a topical steroid anti-inflammatory medication, an eyewear apparatus, and an eye shield. In one non-limiting embodiment, the kit of the invention comprises only the topical non-steroidal anti-inflammatory medication along with an eyewear apparatus and an eye shield.

[0010] The various embodiments of the present invention facilitate the prophylactic administration of at least a non-steroidal anti-inflammatory medication while also providing the patient with approved protective devices in a single convenient it that can be prescribed under a single National Drug Code. In other preferred embodiments, both anti-infective and anti-inflammatory medications are provided with the approved protective devices in a single kit, while still prescribed under a single National Drug Code.

[0011] In one embodiment, the kit may be ordered from a pharmacy through a direct link or portal between the pharmacy and prescribing doctor’s office. The portal is preferably a pre-established computer communications network between the prescribing doctor and pharmacy wherein the doctor submits an electronic prescription for the kit of the invention to a desired pharmacy. The pharmacy receiving the prescription for the kit of the invention then fills the prescription for the patient. Having the entire kit of the invention under a single National Drug Code helps to ensure that all of the components (both medicative and appliances) are provided to a patient when the pharmacy fills the prescription.

[0012] In another embodiment, the antibiotic is a broad spectrum antibiotic. In the preferred embodiment, the antibiotic is selected from a group consisting of gatifloxacin, moxifloxacin, ciprofloxacin, ofloxacin, levofloxacin, besifloxacin or pharmaceutically acceptable equivalents or derivatives thereof. In one aspect of the invention, the antibiotic is preferably a topical eye drop.

[0013] In another embodiment, the non-steroidal anti-inflammatory medication (NSAID) is selected from a group consisting of ketorolac tromethamine, bromfenac, diclofenac, nepafenac or pharmaceutically acceptable equivalents or derivatives thereof. In one aspect of the invention, the NSAID is preferably a topical eye drop.

[0014] In another embodiment, the steroid anti-inflammatory medication (corticosteroid) is selected from a group consisting of prednisolone acetate, dfluprednate, loteprednol etabonate, fluorometholone, or pharmaceutically acceptable equivalents or derivatives thereof. In one aspect of the invention, the corticosteroid is preferably a topical eye drop.

[0015] In another embodiment, the kit of the invention comprises eyewear for shielding the patient’s eyes from light in both the visible and nonvisible spectrums. In one aspect, the eyewear apparatus comprises at least one pair of sunglasses which are wearable over prescription eyeglasses.

[0016] In another embodiment, the kit of the invention comprises a rigid eye shield to be worn by the patient while sleeping. The eye shield is applied with a medical grade tape protecting the patient’s eye from inadvertent contact while sleeping. In one aspect, the eye shield comprises a transparent plastic shield which allows the patient to see with the covered
eye during the night. In another aspect, the eye shield comprises a flexible metal shield with a cushioned periphery.

[0017] In another embodiment, the kit of the invention comprises one or more instruction sheets. The instruction sheets contain anti-infective and anti-inflammatory administration and dosage information. Additionally, the instruction sheets contain information on treatment using the other components of the kit.

[0018] In another embodiment, the kit of the invention comprises a re closable housing or bag, suitable for retaining all of the other components of the kit.

[0019] These and other objects, features and advantages of the present invention become apparent from the following description. When viewed in accordance with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 depicts one embodiment of the kit of the invention; and

[0021] FIG. 2 depicts the portal between a prescribing doctor’s office and networked pharmacies providing the kit of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0022] Controlling the most common post-surgery complications related to cataract and other eye surgeries typically involves prophylactic administration of medications along with protecting the eye from further irritation. An example of such a complication is bacterial conjunctivitis. Ameliorating the inflammatory conditions related to these complications is typically achieved with several eye drops containing anti-infective and anti-inflammatory drugs.

[0023] Positive therapeutic effects have been achieved with patient/self-administered formulations of standard antibiotics, corticosteroids, and non-steroidal anti-inflammatory drugs following cataract surgery to prevent and treat post-operative inflammation and infection.

[0024] After surgery several problems associated with the eye, including inflammation and irritation, can be traced to bacterial infections (e.g., conjunctivitis). It is imperative for proper healing and future ocular health that the eyes are treated against post-surgery infections. It is also important to ensure that the patient physically protects their eyes during the healing process. The post-surgery cataract treatment kit of the invention is adapted to provide for both the medicative therapy and physically shielding the eye from potential damage.

[0025] For convenience and before further description of the present invention, certain terms employed in the specification are collected here. These definitions should be read in light of the remainder of the disclosure and understood as by a person of skill in the art.

[0026] The phrase “effective amount” is an art-recognized term and refers to an amount of an agent that, when incorporated into a pharmaceutical composition of the present invention, produces some desired effect at a reasonable benefit/risk ratio applicable to any medical treatment. In certain embodiments, the term refers to that amount necessary or sufficient to eliminate, reduce or maintain (e.g., prevent the spread of) a symptom of ocular infection, or prevent or treat an ocular infection, such as conjunctivitis. The effective amount may vary depending on such factors as the disease or condition being treated, the particular composition being administered, or the severity of the disease or condition. One skilled in the art may empirically determine the effective amount of a particular agent without necessitating undue experimentation.

[0027] The term “treating” is an art-recognized term which refers to curing as well as ameliorating at least one symptom of any condition or disease.

[0028] The term “preventing” when used in relation to a condition, such as conjunctivitis, is art recognized and refers to administration of a composition which reduces the frequency of, or delays the onset of, symptoms of a medical condition in a patient relative to an individual that does not receive the composition.

[0029] FIG. 1 refers to one embodiment of the post-surgery cataract treatment kit of the invention. The kit comprises a first container comprising an effective amount of antibiotic medicine: a second container comprising an effective amount of a non-steroidal anti-inflammatory (NSAID) medicine; and a third container comprising an effective amount of a corticosteroid anti-inflammatory medicine. In the preferred embodiment, each container is a liquid solution of the respective medicine. The kit further comprises a container holding a nonirritating adhesive tape.

[0030] It should be readily appreciated by one skilled in the relevant arts that while three medications are discussed in relation to the kit, substantially any number of medically appropriate drugs may be included in various embodiments of the invention.

[0031] In one non-limiting embodiment, the antibiotic medicine in container comprises an effective amount of a broad spectrum topical antibiotic eye drop, such as a 0.5% gatifloxacin ophthalmic solution. In other embodiments, the antibiotic can alternatively be an effective amount of oxifloxacin, cirpofloxacin, ofloxacin, levofloxacin, besifloxacin or substantially any pharmaceutically acceptable equivalents or derivatives thereof.

[0032] In one non-limiting embodiment, the NSAID in container comprises an effective amount of a topical non-steroidal anti-inflammatory eye drop, such as a 1% prednisolone acetate ophthalmic suspension. In other embodiments, the NSAID can alternatively be an effective amount of bromfenac, diclofenac, nepafenac or pharmaceutically acceptable equivalents or derivatives thereof.

[0033] In one non-limiting embodiment, the corticosteroid in container comprises an effective amount of a topical corticosteroid anti-inflammatory eye drop, such as a 1% prednisolone acetate ophthalmic suspension. In other embodiments, the corticosteroid can alternatively be an effective amount of difluprednate, loteprednol etabonate, fluorometholone, or pharmaceutically acceptable equivalents or derivatives thereof.

[0034] Gatifloxacin is a prescription medication. As with most prescription antibiotics, the full dosage schedule of gatifloxacin must be com-
pleted to avoid decreasing the drug’s effectiveness and increase the chances that the bacteria may become resistant to gatifloxacin.

[0035] Ketorolac tromethamine ophthalmic solution is a member of the pyrrolo-pyrole group of non-steroidal anti-inflammatory drugs for ophthalmic use. Its chemical name is (±)-5-benzoyl-2, 3-dihydro-1H-pyrrolizine-1-carboxylic acid compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1), and its molecular weight is 376.41. Ketorolac tromethamine is a prescription medication.

[0036] Prednisolone acetate ophthalmic suspension, USP 1% is a topical anti-inflammatory agent for ophthalmic use. Its chemical name is 1113,17,21-Trihydroxyprogna-1,4-diene-3,20-dione 21-acetate. Prednisolone acetate is a prescription medication.

[0037] In another aspect of the invention, the kit 10 includes at least one pair of tinted eyewear 20, commonly known as cataract sunglasses. The sunglasses 20 are preferably provided in a fit-over or wrap-around configuration to accommodate traditional prescription eyeglasses to be worn simultaneously (i.e., behind the sunglasses). In one aspect, the sunglasses 20 are effective to block ultraviolet (UV) rays in addition to providing the standard darkening effect.

[0038] In another aspect of the invention, post-surgery cataract treatment kit 10 further includes at least one commercially available rigid to semi-rigid eye shield 22. Eye shield 22 has a curved profile to provide clearance for the eye and eyelid/eyelashes. Shield 22 is provided to protect the patient’s eye while sleeping to prevent inadvertent contact with the healing eye. The eye shield is applied with a medical grade tape 24. In one aspect, the eye shield comprises a transparent plastic shield which allows the patient to see with the covered eye. In another aspect, the eye shield comprises a flexible metal shield with a cushioned periphery. The eye shield is preferably ventilated to allow free passage of air into and around the covered eye.

[0039] In the preferred embodiment kit 10 also includes a suitable housing 26. The housing 26 may be any type of reclosable package, bag, box, or other means for securing the components of the post-surgery cataract treatment kit 10. Preferably, the housing and various components of the treatment kit 10 are sized so that the components are secured snugly therewithin to prevent unnecessary movement or shifting of the various components. The housing 26 and the components within the housing may also be sized for purposes of economy and/or convenience.

[0040] In another embodiment, the post-surgery cataract treatment kit 10 further comprises one or more instruction sheets 28 containing dosage and administration information coupled with information on using the various components of the kit 10. In another aspect, the dosage and administration information is provided in either instruction manuals or loose leaf paper inserts.

[0041] In still another embodiment, the instructions can be printed in a manual included within the kit 10, on instruction sheets or they may be printed directly on the housing 26. If the instructions are printed on the housing, they may be printed on the outside of the housing or on the inside of the sung where the instructions are not visible to the user of the treatment kit 10 until the user opens the housing. As an alternative, the instructions may be printed on the containers or packaging of the individual components (e.g., 12, 14, 16) of the treatment kit 10.

[0042] In the preferred embodiment, the post-surgery cataract treatment kit 10 described above is assigned a single National Drug Code (NDC) by the United States Food and Drug Administration (FDA). The single NDC code for the three prescription medications 12-16 in addition to the protective devices 20, 22 permit the efficient and convenient ordering and stocking of all the components necessary for a patient to fully address the post-operative treatment of their eye(s). A single NDC code ensures that pharmacies will have the entire kit 10 in stock when filling a prescription.

[0043] In another embodiment, the post-surgery cataract treatment kit 10 only includes one of the medications 12-16, such as the NSAID medication 14, in addition to the protective devices 20, 22. It should be appreciated that this single prescription embodiment simplifies the prosecution of a single NDC code for kit 10.

[0044] As shown in FIG. 2, in one embodiment, the post-surgery cataract treatment kit 10 may be ordered from a pharmacy through a direct link or portal 33 between the pharmacy 32 and prescribing doctor’s office 34. The portal is preferably a pre-established computer communications network 36 between the prescribing doctor and pharmacy wherein the doctor submits an electronic prescription 38 for the kit to a desired pharmacy over network 36. The pharmacy receiving the prescription confirms that the single NDC kit 10 is in stock and fills the prescription for the patient. Having the entire kit of the invention under a single National Drug Code helps to ensure that all of the components (prescription medicines 12, 14, 16 and appliances 20) are provided to the patient when the pharmacy fills the prescription 38.

[0045] This invention is not to be limited by the embodiment shown in the drawings and described in the description, which is given by way of example and not of limitation.

[0046] From the foregoing description, one skilled in the art will readily recognize that the present invention is directed to an improved kit for combination therapy providing anti-infective and anti-inflammatory medicines along with protective hardware for improving overall post-ocular surgery treatment. While the present invention has been described with particular reference to various preferred embodiments, one skilled in the art will recognize from the foregoing discussion and accompanying drawing that changes, modifications and variations can be made in the present invention without departing from the spirit and scope thereof.

1. A kit for use post-operatively by patients who have undergone cataract surgery comprising, in a reclosable container, an assembly of the medications prescribed by the patient’s physician for post-operative use by the patient and protective devices recommended by the patient’s physician for improvement of the patient’s overall treatment, the protective devices comprising sunglasses and eye shields.

2. The kit of claim 1, wherein the post-operative eye medications contained within the kit comprise a topical antibiotic and a topical anti-inflammatory medication.

3. The kit of claim 2, wherein the anti-inflammatory medication comprises a topical non-steroidal anti-inflammatory medication.

4. The kit of claim 1, wherein the assembly in the kit comprises instruction sheets for the components of the kit.

5. The kit of claim 4, wherein the instruction sheets comprise anti-infective and anti-inflammatory administration and dosage information.

6. The kit of claim 1, wherein the reclosable container comprises a bag.
7. The kit of claim 2, wherein the topical antibiotic pharmaceuticals in the kit comprise an effective amount of a broad spectrum topical antibiotic eye drop.

8. The kit of claim 7, wherein the broad spectrum antibiotic is selected from a group consisting of gatifloxacin, moxifloxacin, ciprofloxacin, ofloxacin, levofloxacin, and besifloxacin.

9. The kit of claim 2, wherein the steroidal anti-inflammatory medication is selected from a group consisting of prednisolone acetate, difluprednate, loteprednol etabonate, or fluorometholone.

10. The kit of claim 2, wherein the topical antibiotic is chosen from the group comprising gatifloxacin, moxifloxacin, ciprofloxacin, ofloxacin, levofloxacin, and besifloxacin.

11. A kit for use post-operatively by patients of cataract surgery, the kit being supported in a manually openable and closable container, and comprising a topical antibiotic, a topical non-steroidal anti-inflammatory medication, a topical steroidal anti-inflammatory medication, and an eyewear apparatus.

12. The kit of claim 11, wherein the topical antibiotic is a broad spectrum antibiotic.

13. The kit of claim 12, wherein the broad spectrum antibiotic is selected from a group consisting of gatifloxacin, moxifloxacin, ciprofloxacin, ofloxacin, levofloxacin, and besifloxacin.

14. The kit of claim 11, wherein the non-steroidal anti-inflammatory medication is selected from a group consisting of ketorolac tromethamine, bromfenac, diclofenac, or nepafenac.

15. The kit of claim 11, wherein the steroidal anti-inflammatory medication is selected from the group consisting of prednisolone acetate, difluprednate, loteprednol etabonate, or fluorometholone.

16. A kit for use post-operatively by patients of cataract surgery to improve their recovery, avoid post-operative complications, and increase patient comfort during the healing process, comprising antibiotic medications, anti-inflammatory medications, eyewear for shielding the patient's eye from light in both the visible and near-visible spectrums, and printed instructions for the use of the medications and the eyewear, all disposed in a re closable container.

17. The kit of claim 16, wherein the eyewear contained within the kit comprises a pair of sunglasses which are wearable over prescription eyeglasses.

18. The kit of claim 16, wherein the eyewear comprises an eye shield.